2016-109

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

In re: WEDGEWOOD VILLAGE PHARMACY, INC.,
Petitioner

On Petition for Writ of Mandamus to the United States District Court for the Western District of Missouri in No. 4:15-cv-00687-SRB, Judge Stephen R. Bough.

RESPONSE BRIEF OF EATON VETERINARY PHARMACEUTICAL, INC.,

James J. Kernell
Kyle D. Donnelly
ERICKSON KERNELL
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Attorneys for Eaton Veterinary Pharmaceutical, Inc.

Dated: February 3, 2016

Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

In Re Wedgewood Village v. _____

No. 16-109

CERTIFICATE OF INTEREST

Counsel for the ~~(petitioner) (appellant)~~ (respondent) ~~(appellee) (amicus) (name of party)~~ Eaton Veterinary Pharmaceutical, Inc. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Eaton Veterinary Pharmaceutical, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. ☑ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Erickson Kernell Derusseau & Kleypas, LLC: James J. Kernell, Kyle D. Donnelly

2/3/2016
Date

/s/ James J. Kernell
Signature of counsel

James J. Kernell
Printed name of counsel

Please Note: All questions must be answered

cc: _____

Reset Fields

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MEMORANDUM OF LAW IN OPPOSITION TO WEDGEWOOD'S PETITION FOR WRIT OF MANDAMUS

COMES NOW Eaton Veterinary Pharmaceutical, Inc. ("Eaton"), and hereby opposes the Petition for Writ of Mandamus filed by Petitioner Wedgewood Village Pharmacy, Inc. ("Wedgewood").

RELIEF SOUGHT

Eaton respectfully requests that the Court deny Wedgewood's Petition for Writ of Mandamus.

ISSUE PRESENTED

Did the District Court clearly abuse its discretion by denying Petitioner's motion to transfer when it provided a well-reasoned legal analysis based on the minimal evidence that had been presented to it?

SUMMARY

A writ of mandamus is only appropriate if the district court has committed a clear abuse of discretion. *In re Apple, Inc.*, 602 F.3d 909, 911 (8th Cir. 2010). Petitioner has failed to show that this occurred. The petition is nothing more than a slightly longer, repackaged version of the original motion that was soundly denied by the district court. Petitioner prefaces its petition with a statement that the court failed to conduct a "legally meaningful analysis," however this is directly contradicted by the court's order (Petition, A0001) which properly examined relevant factors based on evidence that had been presented.

The court produced a well-reasoned, 14-page Order that contained a legal analysis wherein the court considered all factors applicable to transfer. This is all that is necessary for a procedural motion such as the motion to transfer filed by Petitioner. Any brevity in the court's opinion is likely because the Petitioner presented no evidence for the court to consider and failed to controvert the evidence presented by Eaton.[1] It is remarkable that Petitioner is now complaining that it did not receive a transfer, especially considering it failed to produce a single piece of evidence in favor of transfer. In short, nothing about the Order represents an abuse of discretion.

Additionally, in an attempt to paint a more favorable picture for this court, Petitioner has omitted key facts from its petition. For example, it fails to mention that it is a registered pharmacy in Missouri (the forum state) and that it has admitted to selling the accused products in the forum state. As noted above, Petitioner has not submitted a single piece of evidence at any point in the case. Every factual assertion made to date is nothing more than unsupported argument of counsel. This petition is nothing more than an attempt at getting a second bite at the proverbial apple – not because the district court's ruling was erroneous but simply because Petitioner did not like the outcome. The fact that courts are given

[1] Although Eaton's Opposition to Petitioner's Motion to Dismiss Complaint or in the Alternative to Transfer Venue is attached as Appx44 to Petitioner's petition, Petitioner failed to include Exhibits A-L constituting 59 pages of uncontroverted evidence (A000154-212).

great discretion when deciding motions to transfer, combined with the fact that the court provided sound legal reasoning means that there can be no abuse of discretion. Accordingly, the petition should be denied.

STATEMENT OF FACTS

This lawsuit was filed to stop and seek damages for Petitioner's ongoing infringement of Eaton's U. S. Patent No. 6,930,127. Petition, A0023. Eaton filed a complaint for patent infringement on September 9, 2015. Petition, A0015. On October 5, 2015, Wedgewood filed a motion to dismiss or, in the alternative, transfer venue. Petition, A0034. After hearing oral arguments on the motion, which consisted of the court questioning the parties at length regarding evidence in the briefs, the court denied the motion in its entirety on December 3, 2015. Petition, A0001. The court's December 3 Order is the subject of Petitioner's petition.

This case has been pending nearly five months and the lawsuit has progressed significantly. The parties have filed numerous motions and other papers as well as attending in-person hearings. The parties have negotiated and filed a Proposed Scheduling Order and Discovery Plan (A000213), the court has issued a Scheduling Order (A000257) and Discovery Confidentiality Order (A000249), Petitioner has answered the complaint (A000228), and Eaton has filed a motion to dismiss the counterclaims, which is still pending (A000247). Finally,

the parties are scheduled to attend a court-ordered mediation on March 2, 2016. A000148.

To consider transferring this case at this point, which would undue months of productive litigation, would prejudice Eaton and would not "secure the just, speedy, and inexpensive determination" of the case required by Fed. R. Civ. P. 1. If the case was transferred to a new venue, especially a venue such as the District of New Jersey that has a larger backlog and takes longer to adjudicate cases than the present venue, all of the progress that has been made in this case would fall victim to the new court's schedule and rules. A000206-211. Also, since mediation is scheduled to be heard by the district court's own mediator, a transfer would postpone mediation for the foreseeable future of this case.

Petitioner is a registered pharmacy in Missouri (the forum state). A000158. It has 30,000 prescribers around the country and ships to all 48 contiguous states, Alaska, Hawaii, and Puerto Rico. A000161, A000164. Petitioner has admitted that it makes and ships non-aqueous formulations of tacrolimus – the infringing chemical composition at issue in the patent – to Missouri. Petition, A0045. In 2007 Petitioner entered into an agency agreement with Midwest Veterinary Supply to supply Petitioner's products to 9,000 veterinary clinics in 27 states. A000167. Midwest Veterinary Supply services veterinary clinics in Missouri from its Des Moines, Iowa and Sun Prairie,

Wisconsin service centers. A000171.

Despite Petitioner's attempt to downplay its contact with Missouri, it has not and cannot argue that it has not had substantial sales in Missouri. Petitioner has provided no reason for transferring the case away from Missouri other than its headquarters is in New Jersey. Further, at the November 17, 2015 hearing on Petitioner's motion to dismiss or transfer, counsel for Petitioner conceded that Petitioner was a registered pharmacy in Missouri, which means that it is subject to disciplinary measures from Missouri authorities. As the District Court correctly concluded, the facts of this case simply do not warrant transferring this dispute.

LEGAL STANDARDS

Mandamus is a drastic remedy, to be invoked only in "extraordinary situations." *Allied Chemical Corp. v. Daiflon, Inc.*, 449 U.S. 33, 34 (1980). It is available only to correct a "clear abuse of discretion" by the court. *In re Apple, Inc.*, 602 F.3d at 911. Three conditions must be satisfied before a writ of mandamus may issue: (1) the party seeking issuance must have no other means to attain the desired relief – "a condition designed to ensure that the writ will not be used as a substitute for the regular appeals process;" (2) the petitioner must establish that it has a "clear and indisputable" right to relief; and (3) "the issuing court, in the exercise of its discretion, must be satisfied that the writ is

appropriate under the circumstances." *Cheney v. U.S. Dist. Court for the Dist.*, 542 U.S. 367, 380-81 (2004); *see also In re ICM, Inc.*, 542 Fed. Appx. 996, 997 (Fed. Cir. 2013).

Under 28 U.S.C. § 1404(a), "[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought[.]" Federal courts "give considerable deference to a plaintiff's choice of forum and thus the party seeking a transfer under section 1404(a) typically bears the burden of proving that a transfer is warranted." *Terra Int'l, Inc. v. Mississippi Chem. Corp.*, 119 F.3d 688, 695 (8th Cir. 1997). If the opposing party would be unduly prejudiced by the passage of time or delay caused by transfer, or if the motion for transfer is a dilatory tactic, the court may deny the motion for transfer. *Am. Standard, Inc. v. Bendix Corp.*, 487 F. Supp. 254, 261 (W.D. Mo. 1980).

On a motion to transfer, the court must "consider the convenience of the parties, the convenience of the witnesses, the interests of justice, and any other relevant factors when comparing alternative venues." *Terra Int'l, Inc.*, 119 F.3d at 696. When analyzing the "convenience" categories, the court may consider "(1) the convenience of the parties, (2) the convenience of the witnesses – including the willingness of witnesses to appear, the ability to subpoena witnesses, and the adequacy of deposition testimony, (3) the accessibility to

records and documents, (4) the location where the conduct complained of occurred, and (5) the applicability of each forum state's substantive law." *Id.*. For the "interest of justice" category, the court may consider "(1) judicial economy, (2) the plaintiff's choice of forum, (3) the comparative costs to the parties of litigating in each forum, (4) each party's ability to enforce a judgment, (5) obstacles to a fair trial, (6) conflict of law issues, and (7) the advantages of having a local court determine questions of local law." *Id.*

ARGUMENT

I. The District Court's Denial of the Motion to Transfer was not a "Clear Abuse of Discretion"

A writ of mandamus is a tool to be used sparingly and only to correct "serious errors." *Mohawk Indus. v. Carpenter*, 558 U.S. 100, 111 (2009); *In re Apple, Inc.*, 602 F.3d 909, 911 (8th Cir. 2010). It is intended to remedy district court orders that amount to "judicial usurpation of power" or "clear abuse of discretion." *Cheney v. United States Dist. Court*, 542 U.S. 367, 390 (2004). Abuse of discretion is present if the district court has based its conclusion on clearly erroneous factual findings or erroneous legal conclusions. *Hosna v. Groose*, 80 F.3d 298, 303 (8th Cir. 1996). The district court in this case has done neither.

Petitioner has not suggested, nor could it, that the district court made erroneous factual findings. The court could not have misinterpreted Petitioner's

facts because Petitioner presented no evidence to interpret. The factual findings necessary for the court's analysis were either based on unsupported assertions made by Petitioner's counsel or evidence produced by Eaton. The facts required for the court's transfer analysis were straightforward and unlikely to be misconstrued. The court did not make erroneous factual findings, thus the only way to find abuse of discretion would be if the court made erroneous legal conclusions.

Courts are given much discretion when deciding motions to transfer. *Terra Int'l, Inc.*, 119 F.3d at 697; *see* 28 U.S.C. § 1404(a). The district court has broad discretion "to adjudicate motions for transfer according to an individualized, case-by-case consideration of convenience and fairness." *Stewart Org., Inc. v. Ricoh Corp.*, 487 U.S. 22, 29 (1988) (citation and internal quotation marks omitted). In our case the district court listed 12 different factors it considered in denying Petitioner's motion to transfer. Petition, A0013. The court applied the few facts presented to it and decided that "the convenience of the parties and the witnesses does not weigh in favor of transfer" and the "interests of justice also weigh against transfer." Petition, A0013. The court gave a valid legal reasoning for its Order – not an erroneous legal conclusion. *Hosna*, 80 F.3d at 303. Because the court did not base its order on clearly erroneous factual findings or erroneous

legal conclusions, there can be no abuse of discretion. Accordingly, the petition must be denied.

II. The Factors Considered for a Motion to Transfer Support the Court's Refusal to Transfer the Case

Section 1404(a) only allows transfer to a clearly more convenient forum, "not to a forum likely to prove equally convenient or inconvenient." *Am. Standard, Inc.*, 487 F. Supp. at 261. The defendant bears the burden of establishing the propriety of a transfer under § 1404(a). *Id.* Petitioner failed to meet this burden, which resulted in its motion being denied. As identified in the court's Order, there are several factors that may be considered for a motion to transfer.

> Under the "convenience" prong of § 1404(a) the court may consider:
>
> (1) the convenience of the parties, (2) the convenience of the witnesses – including the willingness of witnesses to appear, the ability to subpoena witnesses, and the adequacy of deposition testimony, (3) the accessibility to records and documents, (4) the location where the conduct complained of occurred, and (5) the applicability of each forum state's substantive law.

Terra Int'l, Inc., 119 F.3d at 697. Under the "interest of justice" prong the district court may consider:

> (1) judicial economy, (2) the plaintiff's choice of forum, (3) the comparative costs to the parties of litigating in each forum, (4) each party's ability to enforce a judgment, (5) obstacles to a fair trial, (6) conflict of law issues, and (7) the advantages of having a local court determine questions of local law.

Id. However, the plaintiff's choice of forum should not be disturbed unless a balance of relative considerations tips strongly toward the movant. *Enter. Rent-A-Car Co. v. U-Haul Int'l*, 327 F. Supp. 2d 1032, 1046 (E.D. Mo. 2004).

Convenience of the Parties and Witnesses

Witness convenience is one of the most important factors in evaluating a motion to transfer under § 1404(a), with a focus on "key witnesses." *Houk v. Kimberly-Clark Corp.*, 613 F. Supp. 923, 928 (W.D. Mo. 1985); *Am. Standard, Inc.*, 487 F. Supp. at 262. The convenience factor "involves not merely a consideration of the number of witnesses located in or near the respective forums, but the nature and quality of their testimony in relationship to the issues of the case." *Houk v. Kimberly-Clark Corp.*, 613 F. Supp. at 928. The party seeking transfer has the burden to specify clearly what key witnesses will be called and indicate what their testimony will entail. *Id.* The convenience of non-party witnesses carries more weight than convenience of the parties when considering transfer. *See Leverage Leasing Co. v. Lincoln Ins. Co.*, No. 91-0558-CV-W-2, 1991 U.S. Dist. LEXIS 14200, at *5 (W.D. Mo. Sep. 27, 1991)

The crux of Petitioner's argument is that it would be more convenient for it to litigate this case in New Jersey because its employees are there. Petition, p. 3. The convenience of Petitioner's employees, however, is not the most important consideration for the convenience factor. To carry its burden for

transfer, Petitioner needed to identify specific "key witnesses," specifically those that are non-party witnesses. Petitioner failed to do this. In fact, it did not identify any non-party witnesses in New Jersey. By failing to specifically name such witnesses, Petitioner has not met its burden to show that convenience of the witnesses favors New Jersey. *Enter. Rent-A-Car Co.*, 327 F. Supp. 2d at 1046 ("'It is the burden of the party seeking transfer to specify clearly the key witnesses to be called and indicate what their testimony will entail'. . . [The movant] has not met this burden, as it does not provide the Court with the names of any proposed witnesses or even the general nature of their testimony, and instead merely states that all witnesses are located in [the proposed transfer venue].".)

Petitioner's liability for infringement will be determined based on customer use of the accused products. Key witnesses for this inquiry are customers that received and used the accused products. This lawsuit was filed in Missouri because Eaton became aware of infringement occurring there. Petition, A0016. Petitioner has admitted that it shipped the accused product to customers in Missouri. Petition, A0045. Many key non-party witnesses will consist of customers in Missouri that received and used the accused product.

Because Petitioner has not specifically named any key witnesses in New Jersey, or provided any type of evidentiary basis for its contention that New Jersey is more convenient for witnesses or the parties, it has failed to meet its

burden for the first two factors. Therefore, these factors weigh against transfer to New Jersey.

Location of the Documents

Petitioner argues that because relevant documents are located at its office in New Jersey, that state is a more convenient forum. Petition, p. 11. However, Petitioner offers no evidence as to what these relevant documents might be, how expansive the document list is, or why transporting the necessary documents would be prohibitively expensive or inconvenient for them. This is not a document-intensive case. Petitioner has admitted that it sells non-aqueous tacrolimus. Petition, A0045. It is the method of administering the non-aqueous tacrolimus that is at issue. Further, discovery is typically conducted electronically, without the need to physically transport documents.

Additionally, it is likely that Missouri witnesses (customers that purchased and used the accused product) will have relevant documents. While the parties will be obligated to produce documents regardless of where the case is heard, the obligations of non-party witnesses are geographically constrained. Accordingly, a Missouri court is the proper court to issue subpoenas for documents from Missouri witnesses. Therefore, due to Petitioner's failure to offer any evidence showing that this factor favors transfer, combined with the fact that key

witnesses and their documents are located in Missouri, this factor weighs against transfer to New Jersey.

The Location Where Infringement Occurred

Infringement occurred in Missouri. Petition, A0016. Despite Petitioner's argument that all of its sales take place in New Jersey, this court has held that a sale – and consequently infringement associated with the sale – may be deemed to have occurred at the location of the buyer. *See North Am. Philips Corp. v. Am Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994) ("We hold that to sell an infringing article to a buyer in Illinois is to commit a tort there . . ."). Further, it is not the sale of the product per se that constitutes infringement in this case, but the method of application and use by the customer in Missouri. The situs of injury in a patent infringement case is the location, or locations, where infringing activity impacts the interests of the patentee, which is usually the place of infringing sales. *See Beverly Hills Fan Co. v. Royal Sovereign Corp.*¸21 F.3d 1558, 1571 (Fed. Cir. 1994). Thus, because infringement occurred in Missouri, this factor weighs against transfer to New Jersey.

Applicability of State Substantive Law

This dispute involves only questions of federal law. Therefore, this factor is neutral.

Judicial Economy

Petitioner argues that judicial economy favors transfer to New Jersey. However, once again, Petitioner provides no evidence in support. Objectively, the interests of justice favor Missouri. Based on data compiled by the Federal Judiciary, in 2014 the District of New Jersey had more than four times as many cases pending as the Western District of Missouri. A000202-203. The data also indicates that the Western District of Missouri had a shorter case pendency time than the District of New Jersey in 2014. The Western District of Missouri had a median pendency of 23.3 months for cases that went to trial. A000206-207. The District of Jersey had a median pendency of 36.8 months for cases that went to trial. *Id*. Further, the case load per judge in the District of New Jersey is more than 2.5 times the case load per judge in the Western District of Missouri. A000211. Because the District of New Jersey is operating with a higher case load, a longer case pendency time, and a high case load per judge, the Western District of Missouri would likely provide an easier and more expeditious venue for this dispute. Therefore, this factor weighs against transfer to New Jersey.

Weight Accorded to Plaintiff's Choice of Forum

Plaintiff's choice of forum should not be disturbed unless a balance of relative considerations tips strongly toward the movant. *Enter. Rent-A-Car Co. v. U-Haul Int'l*, 327 F. Supp. 2d 1032, 1046 (E.D. Mo. 2004). Therefore, this factor weighs against transfer to New Jersey.

Comparative Costs of Litigating in Each Forum

Like every other factor, Petitioner has provided no evidence to suggest that New Jersey would be a less expensive forum for litigation. Petitioner halfheartedly attempts to use travel expenses for its company employees as a reason that New Jersey would be cheaper, but it provides no analysis for its general statements. For example, Petitioner seems to suggest that many if not all "relevant witnesses" in its company (Petitioner identifies pharmacists, marketing staff, and all levels of management as examples of such witnesses) will travel to Missouri for this case. Petition, pp.18-19. It is highly unlikely that Petitioner is going to fly a legion of employees to Kansas City every time there is a court hearing. So far, not a single employee of Petitioner has attended a hearing in Kansas City.

Petitioner's hollow transfer analysis using broad unsupported generalizations, rather than reasoned analysis supported by evidence, is undoubtedly part of the reason the court denied transfer. Because Petitioner has

not shown that New Jersey would be a less expensive forum for litigation, this factor weighs against transfer.

Ability to Enforce a Judgment

This dispute involves only questions of federal law, therefore a judgment could be enforced regardless of which court issues it. Accordingly, this factor is neutral.

Advantages of Having a Local Court

While this dispute does not implicate state or local law, the Eighth Circuit has stated that "[j]ury duty is a burden that ought not to be imposed upon the people of a community which has no relation to the litigation. In cases which touch the affairs of many persons, there is reason for holding the trial in their view and reach rather than in remote parts of the country. . ." *K-V Pharm. Co. v. J. Uriach & CIA, S.A.*, 648 F.3d 588, 597 (8th Cir. 2011) (quoting *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 504 (1947)). Because infringement occurred in Missouri and affected Missouri residents, the case should be heard in Missouri. This is especially appropriate considering Petitioner is a registered pharmacy in Missouri (A000158) and selling drugs to Missouri residents (Petition, A0045). Accordingly, this factor weighs against transfer to New Jersey.

Obstacles to a Fair Trial and Conflict of Law Issues

Eaton is unable to identify any issues related to conflict of laws or obstacles to a fair trial. Therefore, these factors are inapplicable or neutral.

CONCLUSION

After considering all relevant transfer factors, none weigh in favor of transfer. Eight factors weigh against transfer and four are neutral or inapplicable. Petitioner has utterly failed to show that it has a "clear and indisputable" right to relief as required for a writ of mandamus. *Cheney*, 542 U.S. at 381. Accordingly, the petition must be denied.

Because Petitioner has not shown that the district court abused its discretion, or that Petitioner has a "clear and indisputable" right to relief, Eaton respectfully requests that the court deny the petition for writ of mandamus.

Respectfully submitted,

By: */s/ James J. Kernell*
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ERICKSON, KERNELL, DERUSSEAU & KLEYPAS, LLC

Patent, Trademark and Copyright Matters

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Leawood, Kansas 66206

JAMES J. KERNELL
Admitted in Kansas and Missouri
Email: jjk@kcpatentlaw.com

October 16, 2014

UPS NEXT DAY

Wedgewood Pharmacy
405 Heron Drive, #200
Swedesboro, NJ 08085

Re: Eaton Veterinary Pharmaceuticals, Inc.
U.S. Patent No. 6,930,127

Dear Sir/Madame:

We represent Eaton Veterinary Pharmaceuticals, Inc. for intellectual property matters. Eaton is the owner of U.S. Patent No. 6,930,127 for Veterinary Treatment of Ophthalmic Disease in Animals Using Topical Tacrolimus in a non-aqueous vehicle. A copy of the patent is enclosed for your review.

It has come to our attention that your company is compounding and selling a tacrolimus composition in a non-aqueous vehicle that may or may not be combined with other ingredients such as cyclosporin. We believe that your product falls within the scope of the '127 patent claims. In order to resolve this matter, we are asking that you cease and desist compounding tacrolimus in a non-aqueous vehicle. Understanding that you may desire to continue providing this patented formula to your clients, we are offering to license your pharmacy in this letter under the patent on the following terms:

1. An upfront license fee of $1,000 submitted with a signed copy of this letter;

2. $8.00 per tube or other dispensed container paid quarterly on future sales from the date of this letter; and

3. Sales reports submitted quarterly with the right to audit sales records semi-annually.

EXHIBIT

We request a written response by October 31, 2014 to avoid further action in this matter. If you have any questions or would like to discuss this offer, please do not hesitate to call.

Sincerely yours,

ERICKSON KERNELL DERUSSEAU & KLEYPAS, LLC

By: _____
James J. Kernell

JJK/ljk

Enclosure: U.S. Patent No. 6,930,127

cc: Eaton Veterinary Pharmaceuticals, Inc. (w/o enc.)

_____Our company would like to continue compounding tacrolimus ophthalmic in a non-aqueous vehicle by submitting the $1000 fee and agreeing to the royalty arrangement.

_____ Signature

_____ Name

_____ Title

_____Our company will cease and desist from compounding tacrolimus ophthalmic in a non-aqueous vehicle immediately.

_____ Signature

_____ Name

_____ Title

EXHIBIT C

ERICKSON KERNELL ip

May 8, 2015

FEDERAL EXPRESS

Wedgewood Pharmacy
405 Heron Drive, #200
Swedesboro, New Jersey 08085

Re: Eaton Veterinary Pharmaceuticals, Inc. -
U. S. Patent No. 6,930,127

Dear Sir or Madam:

We represent Eaton Veterinary Pharmaceuticals, Inc. for intellectual property matters. Eaton is the owner of U. S. Patent No. 6,930,127 for "Veterinary Treatment of Ophthalmic Disease in Animals Using Topical Tacrolimus" in a non-aqueous vehicle. A copy of which was previously sent to you on October 16, 2014.

It is our understanding that Wedgewood Pharmacy is continuing to compound and sell a tacrolimus composition in a non-aqueous vehicle that may or may not be combined with other ingredients such as cyclosporin. As we previously wrote, we believe that your product falls within the scope of the '127 patent claims. In order to resolve this matter, we are asking that you cease and desist compounding tacrolimus in a non-aqueous vehicle. Understanding that you may desire to continue providing this patented formula to your clients, we are again offering to license your pharmacy in this letter under the patent on the following terms:

1. An upfront license fee of $1,000 submitted with a signed copy of this letter;

2. $8.00 per tube or other dispensed container paid quarterly on future sales from the date of this letter; and

3. Sales reports submitted quarterly with the right to audit sales records semi-annually.

We request a written response by May 15, 2015 to avoid further legal action in this matter.

EXHIBIT

James J. Kernell • jjk@kcpatentlaw.com • Admitted in Kansas and Missouri
Erickson Kernell IP, LLC • 8900 State Line Road • Suite 500 • Leawood, Kansas 66206
Direct: 913.499.1350 • Phone: 913.549.4700 • Fax: 913.549.4646

If you have any questions or would like to discuss this offer, please do not hesitate to call.

Sincerely yours,

ERICKSON KERNELL DERUSSEAU
& KLEYPAS, LLC

By: _____
James J. Kernell

JJK/ljk

cc: Eaton Veterinary Pharmaceuticals, Inc.

_____Our company would like to continue compounding tacrolimus ophthalmic in a non-aqueous vehicle by submitting the $1,000 fee and agreeing to the royalty arrangement.

_____ Signature

_____ Name

_____ Title

_____Our company will cease and desist from compounding tacrolimus ophthalmic in a non-aqueous vehicle immediately.

_____ Signature

_____ Name

_____ Title

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI

Case Number: 4:15-cv-00687-SRB

NOTICE OF INCLUSION IN THE MEDIATION AND ASSESSMENT PROGRAM

This is notice that your case is included in the Western District of Missouri's Mediation and Assessment Program or "MAP." You should carefully review the Court's General Order for the Mediation and Assessment Program (the "General Order") for Program requirements, including your obligation to serve this Notice. The General Order is located on the Court's website at www.mow.uscourts.gov/district/map.html and was restated effective August 1, 2013.

Your case has been randomly assigned to the following category in the Mediation and Assessment Program:

____ United States Magistrate or United States Bankruptcy Judge

X Director of the Mediation and Assessment Program

____ Outside Mediator

JUDGE ASSIGNMENT

If your case has been assigned to a Judge for mediation, you will be notified of the date, time and place of a settlement conference by the Judge's office after responsive pleadings are filed. The mediation shall occur no later than 75 calendar days after the Rule 26(f) meeting as required by the Federal Rules of Civil Procedure ("Rule 26 meeting"), unless otherwise scheduled by the Judge.

DIRECTOR ASSIGNMENT

If your case has been assigned to the Director of MAP for mediation, you will be notified by the Director's office of the date, time and place of either a teleconference or a mediation after responsive pleadings are filed. The mediation shall occur no later than 75 calendar days after the Rule 26 meeting, unless otherwise scheduled by the Director.

OUTSIDE MEDIATOR ASSIGNMENT

If your case has been assigned to an Outside Mediator, **the parties have 14 calendar days after the Rule 26 meeting to select an Outside Mediator, schedule a mediation and file a Designation of Mediator certificate** (ADR event in ECF) stating the name of the Outside Mediator, and the date, time and place of the in-person mediation. The certificate must be signed by or on behalf of each party.

The mediation shall occur no later than 75 calendar days after the Rule 26 meeting.
Within ten (10) calendar days of the mediation or other ADR option session, the Mediator and parties (pro se or by counsel) shall submit a status report (separately or jointly, and preferably by facsimile or email) to the Director. The report should state how long the mediation lasted, whether all required parties were present in person, the outcome of the session, and whether additional settlement discussions would be productive and at what point in time or after what specific events.

CONTINUING OBLIGATIONS

Inclusion in the Mediation and Assessment Program does not relieve you of any of the obligations or deadlines that you have in this lawsuit. IF YOU HAVE BEEN SERVED, YOU MUST FILE A TIMELY RESPONSE IN ORDER TO AVOID THE RISK OF A DEFAULT JUDGMENT.

MEDIATION

Mediation is a process in which a neutral third party assists the parties in developing and exploring their underlying interests (in addition to their legal positions), promotes the development of options and assists the parties toward settling the case through negotiations.

As a party to a lawsuit in this Court, you are entitled to pursue all claims or defenses to claims that you have asserted until a disposition of the claims or defenses is made by the Court or a jury. However, most of the lawsuits filed in this and other courts are resolved by voluntary settlement of the parties before trial. With a settlement, the expense and inconvenience of litigation can be reduced and the uncertainty of the outcome can be eliminated.

Good faith participation in the Mediation and Assessment Program is required, but you are not required to settle the case.

It is important that you carefully review and objectively evaluate your case prior to the first mediation or other ADR option session. You should come prepared to discuss and negotiate the settlement of your case.

ATTENDANCE AT MEDIATION

Please note that lead trial counsel and parties are required to attend mediations in person. In-person attendance of additional individuals is also required when applicable (e.g. insurance company representatives). See Section V.E. of the General Order.

The failure to attend mediation or other ADR option session, or the refusal to cooperate or timely cooperate in the Program, may result in the imposition of sanctions by the assigned Judge.

Mediation and Assessment Program
Jill A. Morris, Director
Charles Evans Whittaker Courthouse
400 E. 9th Street, Room 3238
Kansas City, Missouri 64106
816-512-5080
816-512-5089 (facsimile)
map@mow.uscourts.gov

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

EATON VETERINARY PHARMACETUICAL, INC.,	)	
Plaintiff,	)	
v.	)	Case No. 4:15-cv-00687-SRB
WEDGEWOOD VILLAGE PHARMACY, INC.,	)	
Defendant.	)	

AFFIDAVIT OF JAMES J. KERNELL

STATE OF KANSAS)
) ss.
COUNTY OF JOHNSON)

I, James J. Kernell, being duly sworn upon my oath do state and affirm to the best of my knowledge and belief that:

1. My name is James J. Kernell. I am over 18 years of age. I have never been convicted of a felony. I am competent to attest to the factual matters set forth in this affidavit.

2. Attached as Exhibit A is a true and correct copy a webpage from www.wedgewoodpharmacy.com captured October 22, 2015.

3. Attached as Exhibit B is a true and correct copy of a webpage from renew.pr.mo.gov/pharmacy-licensee-searhc-detail.asp captured October 21, 2015.

4. Attached as Exhibit C is a true and correct copy of a webpage from www.wedgewoodpharmacy.com captured October 13, 2015.

5. Attached as Exhibit D is a true and correct copy of a webpage from www.wedgewoodpharmacy.com captured October 6, 2015.

6. Attached as Exhibit E is a true and correct copy of a webpage from www.wedgewoodpharmacy.com captured October 6, 2015.

7. Attached as Exhibit F is a true and correct copy of a webpage from www.midwestvet.net captured October 21, 2015.

8. Attached as Exhibit G is a true and correct copy of a document downloaded from the Missouri Secretary of State's website on October 22, 2015.

9. Attached as Exhibit H is a true and correct copy of a webpage from www.iawofcompoundingmedications.com captured October 21, 2015.

10. Attached as Exhibit I is a true and correct copy of a webpage from www.wedgewoodpetrx.com captured October 21, 2015.

11. Attached as Exhibit J is a true and correct copy of a document downloaded from www.uscourts.gov/statistics-reports/federal-judicial-caseload-statistics-2014-tables on October 22, 2015.

12. Attached as Exhibit K is a true and correct copy of a document downloaded from www.uscourts.gov/statistics-reports/federal-judicial-caseload-statistics-2014-tables on October 22, 2015.

13. Attached as Exhibit L is a true and correct copy of a document downloaded from trac.syr.edu/tracreports/judge/364 on October 13, 2015.

FURTHER AFFIANT SAYETH NAUGHT.

JAMES J. KERNELL

Subscribed and sworn to before me, a Notary Public, this 22nd day of October, 2015.

Notary Public

SEAL

My Commission Expires:

6/8/2016

EXHIBIT A

Webpage Screenshot

Customer Care

We have a world-class team of pharmacists, compounding and dispensing technicians, and customer care specialists to make filling your prescription with us quick and easy. From convenient 24/7 online access through home delivery and refill reminders, our service is second to none.

Medicine For People

When you need a custom compounded medication, trust Wedgewood Pharmacy.

- Visit WedgewoodRx.com
- Prescribe Now
- Order online refills
- Request insurance form

Medicine For Pets

Join the thousands of veterinarians and pet owners who turn to Wedgewood Pharmacy.

- Visit WedgewoodPetRx.com
- Order online refills
- Online Prescribing

Newsroom

- Wedgewood Pharmacy receives annual Award for Excellence from the New Jersey Business & Industry Asso
- Wedgewood Pharmacy welcomes New Jersey dignitaries
- Wedgewood Pharmacy welcomes Congressmen and NJBIA
- Nominate Your Vet Tech for Superhero status (and a nice cash reward.)
- Wedgewood Pharmacy now compounds Doxycycline Quad tabs
- Wedgewood Pharmacy is Accredited by the Better Business Bureau
- Lucy Malmberg receives annual award for compounding pharmacy advocacy leadership.
- George J. Malmberg, chief executive officer of Wedgewood Pharmacy, passes away.
- Wedgewood Pharmacy launches Order.WedgewoodPetRx.com for veterinarians

Quality Compounded Medications, Service and Value from Wedgewood Pharmacy

Case 4:15-cv-00687-SRB Document 13-1 Filed 10/22/15 Page 2 of 3

Wedgewood Pharmacy is a PCAB®-accredited compounding pharmacy. As one of the largest

compounding pharmacies in America, we have been serving human-health and animal-health prescribers with custom-compounded medicines since 1981. In fact, more than 30,000 prescribers across the nation turn to Wedgewood Pharmacy for quality, value, choice and service that is legendary. That's because We Care The Way You Care®.

What's Makes Compounding Different?

Compounding is the way all medicines were made until mass manufacturing of drugs began. Most pharmacies dispense these pre-made, manufactured medicines. But for patients who can't take certain drugs because they're allergic to some ingredients, the dosage or dosage form isn't right for them, or the drugs aren't available, their prescribers turn to Wedgewood Pharmacy for custom-compounded medications that are made just for them.

More than 30,000 doctors and veterinarians trust Wedgewood Pharmacy with their patients' health.

When your health, the health of a loved one or a beloved animal in your care depends on custom-compounded medicines, trust Wedgewood Pharmacy. Since 1981, Wedgewood Pharmacy has invested tens of millions of dollars in training, facilities, equipment and procedures to build one of America's largest and most trusted dedicated to compounding.

Wedgewood Pharmacy is PCAB-Accredited.

As the demand for compounded medications has increased, the pharmacy profession saw a need for a system of standards by which each compounding pharmacy can test its quality processes. Compounding pharmacists also wanted a mechanism to allow them to know that they are producing a high-quality compound, and in doing so, providing the best quality to their patients. PCAB Accreditation gives patients, pet owners and prescribers payers a way to select a pharmacy that meets or exceeds the U.S. Pharmacopeia's high quality- standards. We meet or exceed these standards.

Thank you for choosing Wedgewood Pharmacy.

Wedgewood Pharmacy is licensed by the New Jersey State Board of Pharmacy.

405 Heron Drive #200 • Swedesboro, NJ 08085 • (800) 331-8272

EXHIBIT B

Webpage Screenshot

Board Information
Consumers
Complaint Information
General Information
Licensing
Professional Information

Get Pharmacy Board News

General Inquiries

Board of Pharmacy
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573.751.0091 Telephone
573.526.3464 Fax
800.735.2966 TTY
800.735.2466 Voice Relay
MissouriBOP@pr.mo.gov
http://pr.mo.gov/pharmacists

Board of Pharmacy

PR Home » Pharmacy Home

Pharmacy Detail

Pharmacy Primary Source Verification

The licensee search function of this website provides data extracted from our database and constitutes a Primary Source Verification.

Licensee Name:	Wedgewood Village Pharmacy, Inc
Profession Name:	Pharmacy
Licensee Number:	2004011465
Expiration Date:	10/31/2017
Original Issue Date:	5/4/2004
Address:	Anthony Grzib, PIC
Address Con't:	405 Heron Drive Ste 200
City, State Zip:	Swedesboro, NJ 08085
County:	Unknown/Out of State
Practitioner DBA Name:	Wedgewood Pharmacy
Classification:	Class A, D, H

Current Discipline Status:	None

Board of Pharmacy
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573.751.0091 Telephone
573.526.3464 Fax
800.735.2966 TTY
800.735.2466 Voice Relay
MissouriBOP@pr.mo.gov
http://pr.mo.gov/pharmacists

EXHIBIT
A000158

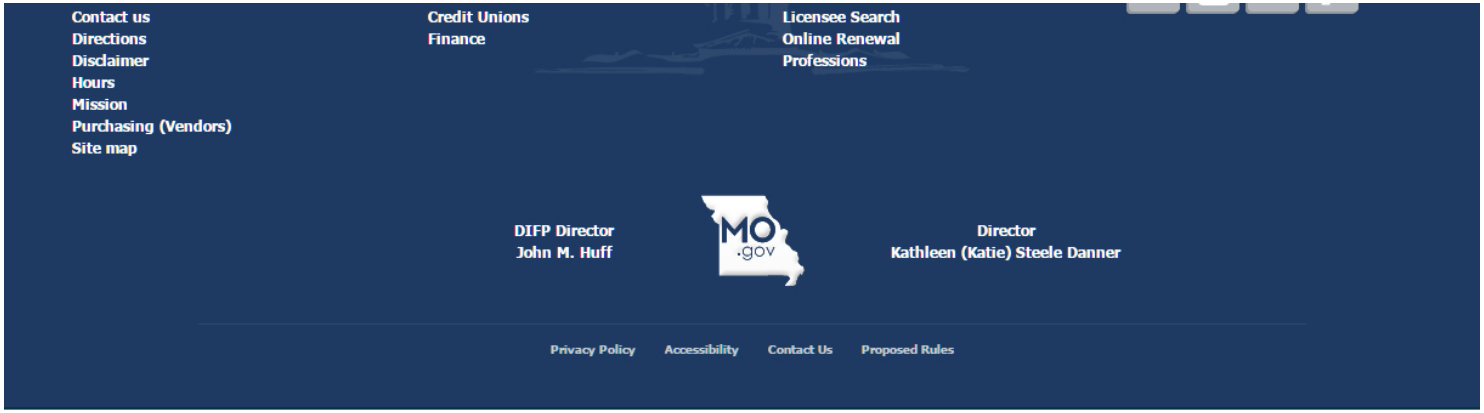

Contact us
Directions
Disclaimer
Hours
Mission
Purchasing (Vendors)
Site map
Credit Unions
Finance
Licensee Search
Online Renewal
Professions
DIFP Director
John M. Huff
MO .gov
Director
Kathleen (Katie) Steele Danner
Privacy Policy
Accessibility
Contact Us
Proposed Rules
https://renew.pr.mo.gov/pharmacy-licensee-search-detail.asp?passkey=1892560 Wed Oct 21 2015 17:58:16 GMT-0500 (Central Daylight Time)

EXHIBIT C

Reliability
Working at Wedgewood Pharmacy
Experience Our Culture
Caring for Our Employees
Leadership Team
Web Site Privacy Policy

WORKING AT WEDGEWOOD PHARMACY

We care the way you care® about your career.

Behind every prescription, there's a patient. Behind every job at Wedgewood Pharmacy, there's a person with skill, dedication and a spirit of innovation. That's why Wedgewood Pharmacy, one of the largest compounding pharmacies in the United States and an acknowledged industry leader, is looking for people who want to excel, grow, innovate and serve.

See current job openings.

More than 30,000 prescribers around the country trust us to deliver high-quality custom medicines to people and the animals they love. We trust our employees to deliver unique medications to the hundreds of thousands of people and animals whose health is our only business.

Wedgewood Pharmacy is a family-owned business founded in 1981 by George and Lucy Malmberg. Our company has grown dramatically because we never stop asking how we can improve patient care while serving our customers better, smarter and faster. To keep growing, we depend on people who thrive on pushing the envelope of innovation in everything we do while keeping a laser focus on patient care.

We offer competitive salaries and benefits and an excellent working environment. We're located in Swedesboro, NJ, a suburban community near Philadelphia, within minutes to the resources of Philadelphia and Wilmington.

If you think you have what it takes to join a company like ours, we invite you to **take a look at the openings available right now**.

EXHIBIT
A000161

405 Heron Drive #200 • Swedesboro, NJ 08085 • (800) 331-8272

EXHIBIT D

405 Heron Drive Suite 200
Swedesboro, NJ 08085
Ph 800.331.8272
www.wedgewoodrx.com

FAQS FOR PATIENTS AND CARE GIVERS

Frequently Asked Questions for Patients and Caregivers

Prescribe Now

Pickup/Refill Now

How do I fill a prescription?

If you already have a written prescription from your prescriber for a compounded medication, it is easy to fill that prescription with Wedgewood Pharmacy. Mail the prescription to:

Home

Wedgewood Pharmacy
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Please make sure you include a telephone number where you can be reached. Your prescriber can also call the prescription in to us toll-free at 877.357.6613.

Once we have your prescription, we will contact you to go over the price of the prescription, or you can call us at 877.357.6613. If you decide to fill it, you will need to provide your shipping and billing information. Payment must be made in advance through check, money order or any major credit card. All prescriptions ship via UPS for delivery within two business days.

If you need to refill a prescription you have already received from Wedgewood Pharmacy, call our customer care specialists at 877.357.6613, or **refill online**.

When are your customer care specialists and pharmacists available?

Our customer care specialists and pharmacists are available Monday through Friday from 8:00 a.m. to 8:00 p.m., and Saturday from 9:00 a.m. to 5:00 p.m., Eastern Time.

How quickly do you process orders?

95% of orders ship within one business day. With rare exceptions, most orders are shipped within 24 hours of receipt, Monday through Friday.

What methods do you use for shipping?

We ship for delivery within two business days. We also ship Next Day upon request. We cannot ship to post office boxes.

Do you ship throughout the United States?

Yes. We ship to the 48 contiguous states, Alaska, Hawaii, Puerto Rico and the Virgin Islands. For those customers outside of our two-day ground service area, we upgrade your packages to second-day air at no additional charge. We're sorry, we cannot ship to North Carolina at this time.

Where is my package?

If we have your e-mail address on file, you will receive an e-mail that contains your shipment information and shipment tracking number. You can also call your customer care specialist at 877.357.6613 for assistance.

How much will my prescription cost?

The price of the prescription depends on the strength, dosage form and package size of the prescribed medication. Wedgewood Pharmacy does require a prescription in advance before we can quote a price, but this does not obligate you to fill your prescription with us.

How can I pay for my prescription?

We accept MasterCard, Visa, Discover and American Express. We also accept checks in advance of shipment.

We do not accept insurance coverage; payment is required upon receipt of medication. We will provide every patient with a universal claim form that can be sent to insurance companies for reimbursement. We cannot guarantee reimbursement and recommend patients contact their insurance agency directly.

Do you provide client counseling?

Yes, pharmacists are available for confidential, professional consultation in-person or via telephone. Our pharmacists and customer care specialists are dedicated solely to compounding and are available to answer any questions that you may have.

What is compounding?

Compounding is the long-established tradition in pharmacy practice that enables practitioners to prescribe and patients to take medicines that are specially prepared by pharmacists to meet patients' individual needs. A growing number of patients have unique health needs that off-the-shelf prescription medicines cannot meet. For them, customized, compounded medications prescribed or ordered by licensed physicians or veterinarians and mixed safely by trained, licensed compounding pharmacists are the only way to better health.

EXHIBIT E

405 Heron Drive Suite 200
Swedesboro, NJ 08085
Ph 800.331.8272
www.wedgewoodpharmacy.com

Wedgewood Pharmacy and Midwest Veterinary Supply sign new agency agreement

10/1/2007

Wedgewood Pharmacy and Midwest Veterinary Supply sign new agency agreement

(*Swedesboro NJ, October 1, 2007*) Wedgewood Pharmacy and Midwest Veterinary Supply, Inc. (Burnsville MN) have entered an agency agreement through which Midwest will represent Wedgewood's compounding pharmacy services to 9,000 veterinary clinics in 27 states. The relationship is effective October 1. This is the first time that Midwest has represented a compounding pharmacy service.

Through the Midwest relationship, Wedgewood's compounding services will be offered to veterinarians through a full-time sales force of more than 100 people.

Wedgewood Pharmacy is the largest veterinary compounding pharmacy in the U.S. and serves more than 20,000 prescribers. Midwest Veterinary Supply is a wholesale distributor of veterinary pharmaceuticals, biologicals, equipment and instruments. The company also provides practice support and in-clinic training services.

A compounding pharmacy creates customized medications for individual patients in response to a licensed practitioner's prescription when a medication is no longer commercially available or is required in a different dosage or form. Wedgewood serves more than 20,000 prescribers nationwide with industry-leading, innovative compounding methods that help to improve animal owner compliance.

For example, Wedgewood recently introduced the Gourmeds™ service, which provides commonly prescribed medications in chewable, naturally flavored tablets that use the same high-quality chicken and fish meals that provide the palatable, proven flavors in leading-brand pet foods. The company also recently introduced Twist-A-Dose™, a new type of syringe-delivery package for transdermal gels that improves accuracy and lowers costs compared with older plunger-type syringes.

About Midwest Veterinary Supply, Inc.

Midwest Veterinary Supply, Inc. is a family/employee-owned full-line distributor of veterinary products including veterinary pharmaceuticals, biologicals, equipment and instruments to more than 9,000 veterinary clinics in 27 states. Headquartered in Burnsville (MN), Midwest represents more than 300 suppliers including most major manufacturers. Its sales force includes both field representatives who call on clinics directly and inside sales-representatives who

EXHIBIT

answer product questions, provide information about promotional programs and service clinic needs over the phone.

Established in 1961, Midwest has five shipping branches that provide next-day delivery and six call centers located in Minnesota, Iowa, Wisconsin, Indiana, Pennsylvania and Maryland. For more information visit www.midwestvet.net

About Wedgewood Pharmacy

A compounding pharmacy creates customized medications for individual patients in response to a licensed practitioner's prescription. Wedgewood Pharmacy is one of the largest compounding pharmacies in the United States, serving more than 25,000 prescribers of compounded medications. It is located in Swedesboro NJ and licensed throughout the United States.

Background: About Compounding Pharmacy

Because every patient is different and has different needs, customized, compounded medications are a vital part of quality medical care. The basis of the profession of pharmacy has always been the "triad," the patient-prescriber-pharmacist relationship.

Through this relationship, patient needs are determined by a prescriber, who chooses a treatment regimen that may include a compounded medication. Prescribers often prescribe compounded medications for reasons that include (but are not limited to) the following situations:

- When needed medications are discontinued by or generally unavailable from pharmaceutical companies, often because the medications are no longer profitable to manufacture;
- When the patient is allergic to certain preservatives, dyes or binders in available off-the shelf medications;
- When treatment requires tailored dosage strengths for patients with unique needs (for example, an infant);
- When a pharmacist can combine several medications the patient is taking to increase compliance;
- When the patient cannot ingest the medication in its commercially available form and a pharmacist can prepare the medication in cream, liquid or other form that the patient can easily take; and
- When medications require flavor additives to make them more palatable for some patients.

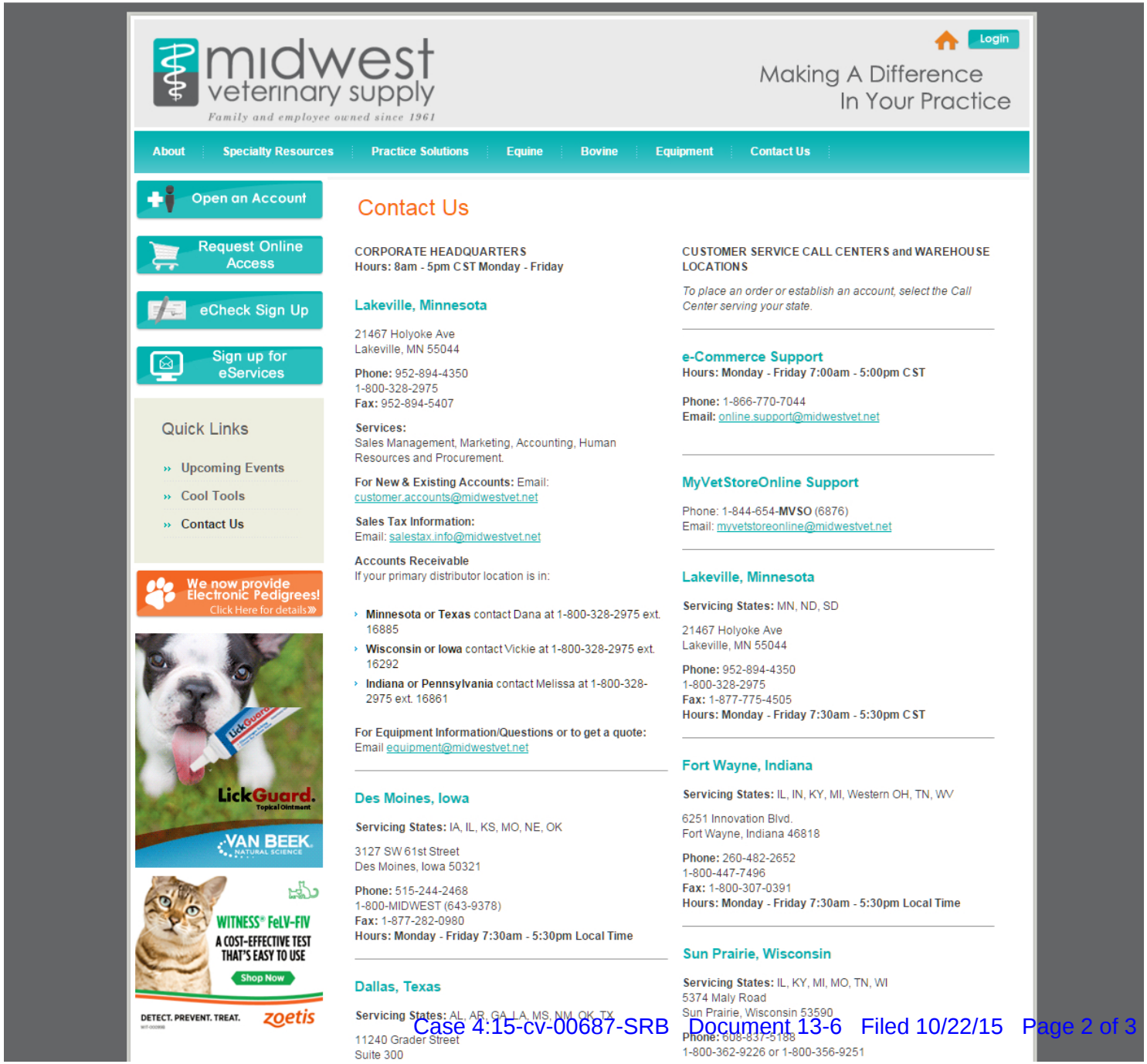
For additional information, visit the International Academy of Compounding Pharmacists' Web site at www.iacprx.org and www.compoundingfacts.org.

back to News and Press Releases Listings >>

405 Heron Drive #200 • Swedesboro, NJ 08085 • (800) 331-8272

EXHIBIT F

Webpage Screenshot



midwest veterinary supply
Family and employee owned since 1961

Login

Making A Difference In Your Practice

About | Specialty Resources | Practice Solutions | Equine | Bovine | Equipment | Contact Us

Open an Account

Request Online Access

eCheck Sign Up

Sign up for eServices

Quick Links

- Upcoming Events
- Cool Tools
- Contact Us

We now provide Electronic Pedigrees!
Click Here for details

Contact Us

CORPORATE HEADQUARTERS
Hours: 8am - 5pm CST Monday - Friday

Lakeville, Minnesota

21467 Holyoke Ave
Lakeville, MN 55044

Phone: 952-894-4350
1-800-328-2975
Fax: 952-894-5407

Services:
Sales Management, Marketing, Accounting, Human Resources and Procurement.

For New & Existing Accounts: Email:
customer.accounts@midwestvet.net

Sales Tax Information:
Email: salestax.info@midwestvet.net

Accounts Receivable
If your primary distributor location is in:

- **Minnesota or Texas** contact Dana at 1-800-328-2975 ext. 16885
- **Wisconsin or Iowa** contact Vickie at 1-800-328-2975 ext. 16292
- **Indiana or Pennsylvania** contact Melissa at 1-800-328-2975 ext. 16861

For Equipment Information/Questions or to get a quote:
Email equipment@midwestvet.net

Des Moines, Iowa

Servicing States: IA, IL, KS, MO, NE, OK

3127 SW 61st Street
Des Moines, Iowa 50321

Phone: 515-244-2468
1-800-MIDWEST (643-9378)
Fax: 1-877-282-0980
Hours: Monday - Friday 7:30am - 5:30pm Local Time

Dallas, Texas

Servicing States: AL, AR, GA, LA, MS, NM, OK, TX

11240 Grader Street
Suite 300

CUSTOMER SERVICE CALL CENTERS and WAREHOUSE LOCATIONS

To place an order or establish an account, select the Call Center serving your state.

e-Commerce Support

Hours: Monday - Friday 7:00am - 5:00pm CST

Phone: 1-866-770-7044
Email: online.support@midwestvet.net

MyVetStoreOnline Support

Phone: 1-844-654-**MVSO** (6876)
Email: myvetstoreonline@midwestvet.net

Lakeville, Minnesota

Servicing States: MN, ND, SD

21467 Holyoke Ave
Lakeville, MN 55044

Phone: 952-894-4350
1-800-328-2975
Fax: 1-877-775-4505
Hours: Monday - Friday 7:30am - 5:30pm CST

Fort Wayne, Indiana

Servicing States: IL, IN, KY, MI, Western OH, TN, WV

6251 Innovation Blvd.
Fort Wayne, Indiana 46818

Phone: 260-482-2652
1-800-447-7496
Fax: 1-800-307-0391
Hours: Monday - Friday 7:30am - 5:30pm Local Time

Sun Prairie, Wisconsin

Servicing States: IL, KY, MI, MO, TN, WI
5374 Maly Road
Sun Prairie, Wisconsin 53590
Phone: 608-837-5188
1-800-362-9226 or 1-800-356-9251

EXHIBIT
A000171

Dallas, TX 75238

Phone: 214-253-4370
1-877-507-6531
Fax: 1-877-486-7641
Hours: Monday - Friday 7:30am - 5:30pm Local Time

Fax: 1-888-372-3941
Hours: Monday - Friday 7:30am - 5:30pm Local Time

Valley Forge, Pennsylvania

Servicing States: CT, DE, ME, MD, MA, NH, NJ, NY, Eastern OH, PA, RI, VT, VA, DC, WV

2420 Boulevard of The Generals
Valley Forge Business Center
Norristown, PA 19403

Phone: 610-539-3770
1-800-583-8020 **(Including Maryland Call Center)**
Fax: 1-800-864-4204
Hours: Monday - Friday 7:30am - 5:30pm Local Time

For comments or suggestions regarding website content please contact us at webadmin@midwestvet.net

Midwest Veterinary Supply is not responsible for pricing, typographical errors, or graphical errors. All items are subject to availability , all prices and rates are subject to change.

midwest veterinary supply

Lakeville, MN	Sun Prairie, WI	Des Moines, IA	Fort Wayne, IN	Valley Forge, PA	Owings Mills, MD	Dallas, TX
1-800-328-2975	1-800-362-9226	1-800-643-9378	1-800-447-7496	1-800-583-8020	1-800-583-8020	1-877-507-6531

https://www.midwestvet.net/contact.html Wed Oct 21 2015 17:31:17 GMT-0500 (Central Daylight Time)

EXHIBIT G

State of Missouri
Creation - General Business - Foreign 3 Page(s)

T0329007059

File Number: 200329310206
Charter # F00547479
Date Filed: 10/17/2003 09:13 AM
Matt Blunt
Secretary of State

Corporations Division
P.O. Box 778, Jefferson City, MO 65102

James
600 W. Main Street, Rm 322, Jefferson City, MO 65101

Application for Certificate of Authority For a Foreign For-Profit Corporation

(Submit in duplicate with filing fee of $155.00)

1. The corporation's name is Wedgewood Village Pharmacy, Inc.

and it is organized and existing under the laws of New Jersey

2. The name it will use in Missouri is Wedgewood Village Pharmacy, Inc.

3. The date of its incorporation was 11/12/1980 (month/day/year), and the period of its duration is Perpetual

4. The address of its principal place of business 279C Egg Harbor Road, Sewell, NJ 08080 (Address / City/State/Zip)

5. The name and address of its registered agent and office in the State of Missouri is

C T Corporation System, 120 South Central Avenue, Clayton, MO 63105
(Name / Address / City/State/Zip)

6. The specific purpose(s) of its business in Missouri are:

Conduct business of a retail pharmacy.

7. The name of its officers and directors and their business addresses are as follows:

(Officers)	Name	Address	City/State/Zip
President	George J. Malmberg	279C Egg Harbor Road	Sewell, NJ 08080
Vice President			
Secretary	Ludmilla P. Malmberg	279C Egg Harbor Road	Sewell, NJ 08080
Treasurer	Ludmilla P. Malmberg	279C Egg Harbor Road	Sewell, NJ 08080

(Board of Directors)

Director	George J. Malmberg	279C Egg Harbor Road	Sewell, NJ 08080
Director	Ludmilla P. Malmberg	279C Egg Harbor Road	Sewell, NJ 08080
Director			

8. The effective date of this document is the date it is filed by the Secretary of State of Missouri, unless you indicate a future date, as follows:

(Date may not be more than 90 days after the filing date in this office)

In affirmation thereof, the facts stated above are true.

(Must be an Officer or Chairman listed in #7, above) | George J. Malmberg, President & CEO (Printed Name) (Title) | 10/10/2003 (Date)

Note: You must submit current original certificate of good standing or certificate of existence with this application. This may be obtained from your Secretary of State or other authority that issues corporate charters.

Corp. #42 (11/01) MO032 - 4/16/02 C T Filing Manager Online

EXHIBIT

A000174

STATE OF NEW JERSEY
DEPARTMENT OF TREASURY
SHORT FORM STANDING

WEDGEWOOD VILLAGE PHARMACY, INC.
0100125942

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Profit Corporation was registered by this office on November 12, 1980.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and registered office are:

George J Malmberg
279-C Egg Harbor Rd
Sewell, NJ 08080

Continued on next page . . .

STATE OF NEW JERSEY
DEPARTMENT OF TREASURY
SHORT FORM STANDING

WEDGEWOOD VILLAGE PHARMACY, INC.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 24th day of September, 2003

John E McCormac, CPA
State Treasurer

State of Missouri

Matt Blunt
Secretary of State

CERTIFICATE OF AUTHORITY

WHEREAS,

WEDGEWOOD VILLAGE PHARMACY, INC.
F00547479

using in Missouri the name

WEDGEWOOD VILLAGE PHARMACY, INC.

has complied with the General and Business Corporation Law which governs Foreign Corporations; by filing in the office of the Secretary of State of Missouri authenticated evidence of its incorporation and good standing under the Laws of the State of New Jersey.

NOW, THEREFORE, I, MATT BLUNT, Secretary of State of the State of Missouri, do hereby certify that said corporation is from this date duly authorized to transact business in this State, and is entitled to all rights and privileges granted to Foreign Corporations under the General and Business Corporation Law of Missouri.

IN TESTIMONY WHEREOF, I have set my hand and imprinted the GREAT SEAL of the State of Missouri, on this, the 17th day of October, 2003.

Matt Blunt

Secretary of State

EXHIBIT H

Webpage Screenshot

The Law of Compounding Medications And Drugs

Human Medications, Human Drugs, Animal Medications, Animal Drugs, Pharmacy law, Pharmaceutical law, Compounding law, Sterile and Non Sterile Compounding 797 Compliance, Veterinary law, Veterinary Compounding Law; Health Care; Awareness of all Types of Compounding Issues; LISTED ON BEST SEARCHING 2012 & 2013; LISTED ON BEST BLOG

Home

Sunday, May 19, 2013

Iowa Board of Pharmacy Finds Probable Cause to File Charges Against Wedgewood Pharamcy for Several Violations

BEFORE THE IOWA BOARD OF PHARMACY
Re:
Iowa Nonresident Pharmacy License of
WEDGEWOOD PHARMACY,
License No. 3577,
Respondent.
Case No. 2012-200
STATEMENT OF CHARGES
& NOTICE OF HEARING
COMES NOW the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges against Wedgewood Pharmacy of 405 Heron Drive, Suite 200, Swedesboro, New Jersey 08085, pursuant to Iowa Code sections 17A.12(2) and i7A.i8(3). Respondent's Iowa nonresident pharmacy license number 3763 was renewed on December 6, 2011.
A. TIME, PLACE, AND NATURE OF HEARING
Hearing. A Disciplinary contested case hearing shall be held on March 12, 2013, before the Iowa Board of Pharmacy. The hearing shall be held during the morning hearing session, beginning at 9:00 a.m. and shall be located in the Board conference room located at 400 S.W. 8th Street, Des Moines, Iowa.
Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the board at hearing.
Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 Iowa Administrative Code rule 35.19. At hearing you will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf, cross-examine witnesses, and examine any documents introduced at hearing. You may appear personally or be represented by counsel at your own expense. The hearing may be open to the public or closed to the public at your discretion.
Prosecution. The office of the Attorney General is responsible for representing the public interest (the State) in this proceeding. Pleadings shall be filed with the Board and copies should be provided to counsel for the State at the following address:
Theresa O'Connell Weeg
Assistant Attorney General
Iowa Attorney General's Office

Search This Blog

Loading...

Purpose of Blog

A blog dedicated to educating pharmacists, doctors, veterinarians, and the general public about the law in the United States relating to compounded medications for both humans and animals

Blog Archive

- ► 2015 (5449)
- ► 2014 (6738)
- ▼ 2013 (5719)
  - ► December (733)
  - ► November (684)
  - ► October (602)
  - ► September (490)
  - ► August (388)
  - ► July (426)
  - ► June (403)
  - ▼ May (496)
    - NABP Testifies at US House Subcommittee Hearing Re...
    - FDA this month signed a nearly $80,000 contract wi...
    - CBO Says House Rx Tracing Bill Would Generate $24 ...
    - FDA MedWatch – Olympia Pharmacy Sterile Compounded...
    - Press Release : The Illinois Department of Public...
    - How Makena, a Controversial Drug to Prevent Preter...
    - Virginia HAS Enacted a compounding law which requi...
    - Fox Business- DANGERS OF COMPOUNDING PHARMACIES Vi...

2nd Floor Hoover State Office Building
Des Moines, Iowa 50319
Ms. Weeg may also be reached by phone at (515) 281-5328 or bye-mail at Theresa.Weeg@iowa.gov.
Communications. You may contact the Board office (515) 281-5944with questions regarding this notice and other matters relating to these disciplinary proceedings. However, you may NOT contact individual members of the Board to discuss these proceedings by phone, letter, facsimile, email, or in person. Board members can only receive information about the case when all parties have notice and an opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case. You may also direct questions relating to settlement of these proceedings to Assistance Attorney General Theresa O'Connell Weegat (515) 281-5328 or at Theresa.Weeg@iowa.gov.
B. LEGAL AUTHORITY AND JURISDICTION
Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147,155A, and 272C(2011).
Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters17A, 147, 148C, and 272C (2011) and 657 Iowa Administrative Code chapter 36.
Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35-21.
C. CHARGES
Count I
FAILURE TO COMPLY WITH PHARMACY COMPOUNDING REQUIREMENTS
Respondent is charged with failing to comply with pharmacy compounding requirements, pursuant to Iowa Code sections 155A.13A(3) and155A.15 and in violation of 657 Iowa Administrative Code 20.1 and 20.3.
Count II
ENGAGING IN THE UNLAWFUL MANUFACTURE OF UNAPPROVED DRUG PRODUCTS
Respondent is charged with the unlawful manufacture and distribution of prescription drug products which are unapproved by the FDA, misbranded and adulterated in violation of Iowa Code sections 126.3, 155A.15(2X1), i55A.23(i)(f) and i55A.23(i)(g); 657 Iowa Administrative Code 20.2 and 20.3(4); 21 U.S.C.§ 355; 21 U.S.C. §352(f)(i); 21 U.S.C. § 351(a)(5); 21 U.S.C. § 352(0); and Title 21 Code of Federal Regulations Parts 210 and 211.
D. FACTUAL CIRCUMSTANCES
1. Respondent is an Iowa nonresident pharmacy. It has been licensed as such since prior to December 4, 2006. Its current license was renewed on December 6, 2011.
2. In its most recent renewal application, Respondent describes itself as "a compounding pharmacy...that provides customized compounded prescription medications upon receipt of prescriptions or orders from licensed practitioners."
3. At all times material to this Statement of Charges, Respondent held a current and active Iowa nonresident pharmacy license.
4. Respondent received a Warning Letter from the U.S. Food and Drug Administration (FDA) dated October 31, 2006. The letter indicated that (1) Respondent produces finished drug products that are essentially copies of commercially available products and (2) Respondent does not document a medical need for particular patients for these versions of otherwise commercially available products. The letter also indicated that (1) Respondent's facility and equipment are of a scale capable of producing large quantities of products and are thus indicative of practice beyond traditional pharmacy compounding and (2) Respondent has manufacturing equipment which can produce large quantities of drugs that are inconsistent with traditional pharmacy compounding. The letter also states "[Respondent] is engaged in the large-scale manufacturing of unapproved drugs, including copies of commercially available FDA-approved drugs, which raises safety

concerns and poses a significant threat to the new drug approval process of the Federal Food, Drug and Cosmetic Act." A copy of the FDA Warning Letter is attached to this Statement of Charges and Notice of Hearing and is hereby incorporated by reference.

5. Respondent received a follow-up letter from the FDA dated June 29, 2012, regarding Respondent's compounding of 17-hydroxyprogesterbne caproate (Makena®). The letter stated "FDA does not consider compounding large volumes of copies, or what are essentially copies, of any approved commercially available drug to fall within the scope of traditional pharmacy practice."The letter also stated, "As we explained in our October 31, 2006, Warning Letter to you, traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children." A copy of the letter is attached to this Statement of Charges and Notice of Hearing and is hereby incorporated by reference.

6. Respondent was inspected by an authorized agent of the Iowa Board of Pharmacy, on December 12, 2012. That inspection report indicates the following:

a. The pharmacist in charge', Anthony Grzib, was unable to generate a report to show which products were shipped into Iowa. As a result, the inspection was extremely limited and the Board's inspector was unable to conduct a complete review of Respondent's facility and records.

b. The Board's inspector was allowed to view several compounding rooms. Those rooms contained large, professional grade equipment.

c. The pharmacist in charge, Anthony Grzib, stated that Respondent is shipping non-patient specific products into Iowa for "office use". This includes products for humans and animals. It also includes sterile and non-sterile products.

d. The pharmacist in charge, Anthony Grzib, stated that Respondent does not have approved New Drug Applications (NDAs) with the FDA for the products that it prepares.

7. On December 24, 2012, the Board received additional information from Respondent, including the following:

a. Between June 12, 2012 and December 11, 2012, Wedgewood dispensed 6.5 patient-specific orders per day into Iowa (1.2 to human patients; 5.3 to animal patients; 3.0 were sterile preparations; 3,3 were non-sterile preparations; and 0.2 were sterile preservative-free preparations).

b. Between June 12, 2012 and December 11, 2012, Wedgewood distributed 11.4 non-patient-specific "office use" orders per day into Iowa (0.4 to prescribers treating • human patients; 11.0to prescribers treating animal patients; 4.8 were sterile preparations; 7.4 were non-sterile preparations; and 0.7 were sterile preservative-free preparations). "Office use" orders, while to one prescriber, may contain more than one compounded preparation.

8. Between June 12, 2012 and December 11, 2012, Respondent dispensed and/or distributed various sterile preparations into Iowa including the following: Amikacin Sulfate, Apomorphine, Cimetidine, Corticotrophin, Cyclosporine, Demecarium Bromide, Desmopressin Acetate, Diphenhydramine, Dipyrone, Edetafe Disodium, Epinephrine, Guaifenesin, Idoxuridine, Lidocaine, Medetomidine, Meloxicam, Methocarbamol, Metoclopramide, Papaverine, Pentosan, Potassium Chloride, Tacrolimus, Trifluridine, Trip'elennamine, Vitamin B-12, Vitamin BComplex, Xylazine, and Sodium Chloride 0.9%.

9. Respondent has dispensed compounded preparations of 17-hydroxyprogesterone caproate to Iowa patients as recently as December 7, 2012.

Contaminated Injections traced to IL clinic
Question of the Day: May 29, 2013 What are the di...
2013 NABP Meeting brochure--Talk Scheduled on Comp...
Alaska Board of Pharmacy Minutes for February 28-M...
Pharmacist Salaries Hit $117K and Keep Climbing
How the Pharmacy Industry Ch-ch-changed in 2012
Armada 2013: Specialty Pharmacy Gets More Competit...
New Drug Trend Forecasts: Express Scripts vs. CVS ...
The Cynical Pharmacist: Pharmacy Compounding And T...
Wow--201 Doctors Named in Scheme to Defraud--Invol...
Markey Proposed Federal Legislation v. Senate HELP...
Iowa Administrative Code Relating to Pharmacies an...
Interesting post about the FDA Inspecting the Room...
Disturbing Parallels Seen in New Compounding Pharm...
Public Warms to FDA in Recent Gallup Poll
Falsified Data, Study Deviations Focus of New Warn...
A prolonged stay: The reason behind the slow pace ...
A Day in the Life of this Blog: Where The Blog Is...
Congressional Consensus on Compounding Reform Stuc...
A NEW SPIN ON THE PROPOSED LEGISLATION--MUST READ:...
TN lists clinics that received suspect steroids ...
Outbreak Pharmacy Had Been in Trouble Before
Question of the Day May 28, 2013 I have posted Te...
ANH Says Compounding pharmacies, essential provide...
Deja ve--FDA tracking down new outbreak tied to co...
KUDOS TO N.J. for hiring pharmaceutical experts to...
Twitter
Update on Countries Viewing Blog-
Report from California
Question of the Day: May 27, 2013 Should Pharmac...
Love 101: The Ring of Fire that Compounding Pharm...
And the 11th and Maybe the Biggest Reason of All t...
Ten Reasons Congress Needs to Give the FDA Jurisdi...
A Decade's Quest for Safer Drugs: Congressional Co...
Slaps on the Wrist Don't Work--
A Dangerous Interplay: Rx Shortages and Med Errors...
5/27/2013: Metro: FDA found 392 drugs to be of poo...
Compounding Pharmacies Experiencing Crackdown By T...
U.S. PIRG Issues Compounding Report
Changes Eyed For Senate Compounding Bill Could Exem...
Unreleased FDA Compounding Guide Becomes Focus

December 7, 2012.
10. Respondent has distributed large quantities of various compounded preparations for non-patient-specific "office use" into Iowa for use as stock supply.
11. In Iowa, "manufacturing", includes the promotion, marketing, or preparationfrombulkdrugsubstances ofcommercially available products for resale by pharmacists,.practitioners, or other persons.
12. Respondent is manufacturing and distributing unapproved new drugs in violation of federal law. Respondent is manufacturing products which are drugs within the meaning of 21 U.S.C. § 321(g)(1) because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or because they are intended to affect the structure or function of the body. These products are "new drugs" within the meaning of 21 U.S.C. § 32i(p) because they are not generally recognized as safe and effective for their labeled uses. Under 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under either 21 U.S.C. §355(b) or (j) is in effect for the product. There are no FDA-approved applications on file for the products manufactured by Respondent. The marketing of these products without an approved application constitutes a violation of federal law.
13. Respondent has engaged in drug manufacturing without complying with CGMP requirements for finished pharmaceuticals as required by 21 U.S.C.§ 351(a)(2)(B) and Title 21Code of Federal Regulations Parts 210 and 211.
E. SETTLEMENT
This matter maybe resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Theresa Weeg.
****
4i
F. PROBABLE CAUSE FINDING
On this IW day of January, 2013, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.
cc: Theresa Weeg
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319
U^C^O^t
SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688
PROOF OF SERVICE
The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:
( ) personal service ( ) first class mail
N) certified mail, return receipt requested •'••( ) facsimile
Article Number 917199999170310560982S ( ) other
on the 111\ day of January, 2013.
I declare that the statements above are true to the best of my information, knowledge and belief.
Lu^^A-g^ b
Debbie S. Jorgenson
Wedgewood Village Pharmacy 31-Oct-06
/—i
Department of Health and Human Services
Telephone (973) 526-6010.
Public Health Service
Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
WARNING LETTER

Of ...
Question of the Day: May 26, 2013 How many illnes...
Louisiana among states that got suspect medicine f...
FDA Could Oversee Some Compounds
US State Rep. Griffith drafting compounding legisl...
Arizona Board of Pharmacy Compounding Task Force M...
March Minutes from Arizona Board of Pharmacy-Updat...
N.C. joins investigation into Tennessee drug compo...
Guest Bloggers Mary Ann Chirba and Alice A. Noble ...
Alabama joining investigation of recalled drugThe ...
TN compounder's steroid sickens patients Inspector...
FORBES: Compounding A Crisis At FDA
Compounding pharmacy group says FDA changed inspec...
Tenn. compounding pharmacy since 1985 investigated...
Health officials investigating complications with ...
Question of the Day May 25, 2013 In light of the R...
Consumer Updates FDA 101: Product Recalls - From ...
A Tennessee compounding pharmacy--Main Street Fami...
USA Today: FDA warns of infections tied to Tennes...
Health officials investigating complications with ...
Health care facilities in at least 13 states recei...
New U.S. fears emerge over tainted compounded ster...
http://www.fda.gov/NewsEvents/Newsroom/PressAnnoun...
Bill to improve compounding pharmacy falls short o...
In Wake of Meningitis Investigation Findings, Heal...
Compounding Pharmacy, Part 2: Preparing for an FDA...
FDA investigating reactions with potentially conta...
FDA warns of infections tied to Tennessee pharmacy...
forbes: Compounding A Crisis At FDA
Question of the Day: May 24, 2013: One report in...
Markey Introduces New Compounding Pharmacy Legisla...
Study calls for crackdown on 'reckless' drug compo...
One Page Summary of Verifying Authority and Legali...
Drug-compounding bill in trouble
AVMA--Veterinary Medicine Mobility Act Finds Legs ...
N.J. hires pharmaceutical experts to help investig...
(Reuters) - Representative Edward Markey, a Democr...
Bill would give veterinarians OK to carry controll...
In Wake of Meningitis Investigation Findings, Heal...
Another Compounding Bill Introduced; the Verifyin...
House GOPs Still Oppose Compounding Bill
Independent Community Pharmacist Testifies at U.S....

October 31, 2006
CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. George Malmberg, R.Ph.
Owner
Wedgewood Village Pharmacy
405 Heron Drive
Swedesboro, New Jersey 08085
06-NWJ-03
Dear Mr. Malmberg:
On October 4-28, 2005, investigators from the U.S. Food and Drug Administration (FDA) inspected, your firm, Wedgewood Village Pharmacy, located at 405 Heron Drive, Swedesboro, NewJersey. This inspection revealed that your firm produces human and animal prescription drugs in various dosage forms and strengths. The inspection also revealed serious violations of the Federal Food, Drug, and Cosmetic Act (FDCA), including violations of its new drug, new animal drug, and misbranding provisions. In particular, and as explained below, the products compounded by your firm are drugs within the meaning of section 201(g) of the FDCA [21 U.S.C. § 321(g)]. These products are new drugs under section 201 (p) of the FDCA [21 U.S.C. § 321 (p)], and new animal drugs under section 201 (v) of the FDCA [21 U.S.C. § 321 (v)], because they are not generally recognized by qualified experts as safe and effective for their labeled uses. These new drugs and new animal drugs, and your production and distribution of them, violate the FDCA.
A. Compounded Drugs Under the FDCA and FDA's Regulatory Approach to Compounding
FDA's position is that the Federal Food, Drug, and Cosmetic Act (FDCA) establishes agency jurisdiction over "new drugs," including compounded drugs. FDA's view is that compounded drugs are "new drugs" within the meaning of 21 U.S.C. § 321 (p), because they are not "generally recognized, among experts ... as safe and effective" for their labeled uses. See Weinberger v. Hynson, Westcott &Dunning, 412 U.S. 609, 619, 629-30 (1973) (explaining the definition of "new drug"). There is substantial judicial authority supporting FDA's position that compounded drugs are not exempt from the new drug definition. See Profls &Patients for Customized Care v. Shalala 56 F.3d 592, 593 n.3 (5th Cir. 1995) ("Although the [FDCA] does not expressly exempt 'pharmacies' or 'compounded drugs' from the new drug . . . provisions, the FDAas a matter of policy has not historically brought enforcement actions against pharmacies engaged in traditional compounding."); In the Matter of Establishment Inspection of: Wedgewood Village Wedgewood Village Pharmacy Pharmacy, 270 F. Supp. 2d 525, 543-44 (D.N.J. 2003), affd, Wedgewood Village Pharmacy v. United States, 421 F.3d 263, 269 (3d Cir. 2005) ("The FDCA contains provisions with explicit exemptions from the new drug .. . provisions. Neither pharmacies nor compounded drugs are expressly exempted."). FDA maintains that, because they are "new drugs" under the FDCA, compounded drugs may not be introduced into interstate commerce without FDA approval.
The drugs that pharmacists compound are rarely FDA-approved and thus lack an FDA finding of safety and efficacy. However, FDA has long recognized the important public health function served by traditional pharmacy compounding. FDA regards traditional compounding as the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient. See Thompson v. Western States Medical Center, 535 U.S. 357, 360-61 (2002). Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.
Through the exercise of enforcement discretion, FDA historically has not taken enforcement actions against pharmacies engaged in traditional pharmacy compounding. Rather, FDA has directed its enforcement resources against establishments whose activities raise the kinds of concerns normally associated with a drug manufacturer and whose compounding practices result in significant violations of the new drug, adulteration, or misbranding provisions of the FDCA.
FDA's current enforcement policies with respect to the compounding of human drugs and compounding of drugs for use in animals are articulated in two Compliance Policy Guide (CPGs).CPG section 460.200 ["Pharmacy Compounding"], issued by FDA on May 29, 2002 (see Notice of Availability, 67 Fed. Reg. 39,409 (June 7, 2002)) addresses the compounding of human drugs. (1The status of Section 503A of the

FDA Voice When Regulators are Ignored Posted on ...
New Hampshire House Bill 313--Status Update
Link to Senate's Proposed Compounding Legislation ...
Pallone Calls for Greater Clarity in Law Regulatin...
PRESCRIPTION FOR DANGER How Unsafe Drugs Produced...
House Subcommittee on Health explores pharmacy com...
IACP Gives Senate Health Committee Feedback On FDA...
FDA Seeks Contractor's Help In Profiling Drug Comp...
Senate Health Committee Passes Alexander and Colle...
Senate HELP Committee attaches amended compounding...
Quality Failures New England Compounding Center--H...
New Report Documents a Decade of Safety Violations...
Gabrielle Cosel Manager, Drug Safety The Pew Char...
Elizabeth Scott (Scotti) Russell Government Affair...
Gerry Migliaccio Quality Systems Consultant Miglia...
Joseph H. Harmison Owner, Harmison Pharmacies On b...
Scott Gottlieb, M.D. Resident Fellow American Ente...
Changes Eyed To Senate Compounding Bill Could Exem...
Delegates Approve Eight Resolutions at the NABP 10...
Question of the Day: May 23, 2013: If Pharmacy L...
FDA Inspections Taking a Toll On Compounders
STATEMENT OF JANET WOODCOCK, M.D. DIRECTOR, CENTER...
Washington Post: Senate panel approves tighter ove...
Second Question of the Day: May 22, 2013 Where Doe...
Harkin aims to Fast-track legislation on Compoundi...
Senate committee advances drug compounding bill
Pharmaceutical Compounding Quality and Accountabil...
Bipartisan Report Finds That Public Health Risks f...
Iowa Board of Pharmacy Charges Against Ameridose L...
Iowa Board of Pharmacy Disciplined DVM Previously
Link to S 957 from HELP Committee: Link to Versi...
What a Great Quote from Senator Mikulski: "Today...
Notice of Committee on Energy and Commerce Subcomm...
More on Track and Trace Bill found at RX Trace Web...
Ranbaxy, FDA, FDASIA and Indian Pharma Credibility...
InBrief: A Track & Trace bill Has Made It To The ...
Senator Mikulski's Remarks regarding Pharmacy Comp...
Nathan Dunlap Death Penalty Case: ACLU Files ...
Meningitis: Compounding bill emerges from Senate ...

FDCA ["Pharmacy Compounding"] [21 U.S.C. § 353a] was addressed by the Supreme Court in Thompson v. Western States Medical Center, 535 U.S. 357 (2002)) 'CPG section 608.400 ["Compounding of Drugs for Use in Animals"], issued in revised form by FDA's Center for Veterinary Medicine on July 8, 2003, addresses the compounding of drugs for use in animals.

These CPGs identify factors that the Agency considers in deciding whether to initiate enforcement action with respect to compounding. These factors help differentiate the traditional practice of pharmacy compounding from the manufacture of unapproved new drugs and unapproved new animal drugs. They further address compounding practices that result in significant violations of the new drug, adulteration, or misbranding provisions of the FDCA. As stated in the CPGs, the factors listed in the CPGs are not intended to be exhaustive. See CPG section 460.200 ["Pharmacy Compounding"] ("The . . . list of factors is not intended to be exhaustive .") and CPG section 608.400 ["Compounding of Drugs for Use in Animals"j ("The . , . list of factors is not intended to be all inclusive.")

B. CPG on Compounding of Human Drugs [CPG 460.200]

CPG 460.200 addresses the factors that the agency considers in determining whether to exercise its enforcement discretion with respect to the, compounding of human drugs. Some of the factors identified in the CPG on human compounding include considering whether a firm

uses commercial scale manufacturing equipment or testing equipment for compounding drug products;

compounds drugs that are copies, or essentially copies, of commercially available FDA-approved drug products without a documented patient-specific medical need.

C. CPG on Compounding of Drugs for Use in Animals [CPG 608.400]

CPG 608.400 addresses the factors that the agency may consider in determining whether to initiate regulatory action with respect to the illegal compounding of drugs for use in animals. Some of the factors identified in this CPG include considering whether a firm:

compounds drugs for use in animals where an approved new animal drug or approved new human drug used as labeled or in conformity with Title 21 Code of Federal Regulations Part 530 will, in the available dosage form and concentration, appropriately treat the condition diagnosed;

compounds finished drugs from human or animal drugs that are not the subject of an approved application, or from bulk drug substances, other than those specifically addressed for regulatory discretion by the FDA, Center for Veterinary Medicine; or

uses commercial scale manufacturing equipment for compounding drug products

As discussed below, our inspection revealed the scope and nature of your activities are clearly outside the bounds of traditional pharmacy practice and that these activities have resulted in significant violations of the new animal drug provisions of the FDCA.

D. Inspectional Findings

As a result of our inspection of your firm, our findings include the following:

1. Your firm produces finished drug products that are essentially copies of commercially available products, and your firm does not document a medical need for particular patients for these versions of otherwise commercially available products. These products include:

Enrofloxacin (veterinary)
Pyrimethamine/Sulfadiazine (veterinary)
Cyclosporine Ophthalmic (veterinary)
Altrenogest (veterinary)
Flunixin Meglumine (veterinary)
Ketoprofen (veterinary)
Acetic Acid 2% solution (human)
Dipyridamole 5 mg/mL injections (human)
DMSO (Dimethylsulfoxide) 50% aqueous solutions (human) EDTA (Edetate Disodium) 150 mg/mL injections (human) Estradiol Valerate Oil 10 mg/mL and 20 mg/mL injections (human) Hyaluronidase 150 units/mL injections (human)
Isosulfan injections (human)
Lidocaine 2% surgical jelly (human)
Mesalamine 500 mg suppositories (human)
Mitomycin Ophthalmic solutions (human)
Naloxone HCl 1 mg/mL injections (human)
Progesterone in Oil 50 mg/mL injections (human)
Ranitidine 15 mg/mL solutions (human)

Harkin Statement on HELP Committee Passage of the ...
Viewing of the Senate Hearing on Compounding on Ma...
Pharmacy compounding reform bill headed to Senate ...
Victims Of Fungal Meningitis Outbreak Deserve Comp...
States Take On Unregulated Pharmaceutical Faciliti...
Lawsuit alleges meningoencephalitis caused by inje...
Strenghten the FDA Michael PhelanAttorney (866) 73...
Pharmalot-Ophthalmologists Balk At Senate Compound...
DEA v. Top RX Pharmacy Order
Pharmacy: Issues in pharmacy--Countries that Allow...
Pharmacy Podcast Episode 85 David Miller with IACP...
Viewing of House Energy & Commerce Committee Heari...
Reminder: Both the Senate and the House Are Holdi...
Question of the Day: May 22, 2013 If the GOA does ...
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Sodium Tetradecyl Sulfate 3% injections (human)
Tacrolimus 0.1 % ointments (human)
Tinidazole 500 mg capsules (human)
2. Your facility and equipment are of a scale capable of producing large quantities of products and are thus indicative of practice beyond traditional pharmacy compounding. Specifically, your facility contains [redacted]rooms used for production, including raw material storage, weighing, and [redacted] sterile suites. Equipment contained within these processing rooms is capable of producing large quantities of drug products. For example, the [redacted] encapsulator is capable of producing [redacted] capsules per hour and the [redacted] Mixer has a capacity of [redacted]. This manufacturing equipment produces large quantities of drugs, including lot sizes of drugs that are inconsistent with traditional pharmacy compounding. Examples of lot sizes produced by your firm include, but are not limited to:
Diethylstilbestrol 1 mg capsule - [redacted] capsules (veterinary or human)
Dipyrone 500 mg/ml injection [redacted] (veterinary)
Flunixin Meglumine paste 1.5 mg/30 ml - [redacted] (veterinary)
Girseofulvin 2.5 gm/10 gm packet - [redacted] packets (veterinary)
17-alpha Hydroxyprogesterone Caproate injection - [redacted]
(veterinary or human)
Lidocaine 2% jelly 1000 ml - [redacted] (human)
Your firm purports to be a compounding pharmacy. But our inspection revealed that your firm engages in activities that fall outside the traditional practice of pharmacy compounding of drugs. We base this conclusion on the factors in CPG 460.200, and CPG 608.400 including the factors identified above. Your firm is engaged in the large scale manufacturing of unapproved drugs, including copies of commercially available FDA-approved drugs, which raises safety concerns and poses a significant threat to the new drug approval process of the FDCA.
E. Violations of the FDCA
Based on the foregoing findings, your firm and the drugs that your firm produces violate the following provisions of the FDCA:
1. Unapproved New Drugs Under Section 505 of the FDCA f21 U.S. C.S 3551
The human drug products produced by your firm are unapproved new drugs within the meaning of section 505 of the FDCA [21 U.S.C. § 355] and may not be introduced into interstate commerce without an FDA-approved drug application.
2. Misbranded Drugs Under Section 502ffl(1) of the FDCA T21 U.S.C. S352(f)(1)l
Your human and animal drug products are misbranded under section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] in that their labeling fails to bear adequate directions for use. These products are not exempt from section 502(f)(1) under 21 C.F.R. § 201.115 because they are new drugs within the meaning of section 201 (p) of the FDCA [21 U.S.C. § 321 (p)], or new animal drugs within the meaning of section 201 (v) of the FDCA [21 U.S.C. § 321 (v)], and they lack approved applications filed pursuant to sections 505 or 512 of the FDCA [21 U.S.C. §§ 355 and 360b].
3. Adulterated Animal Drugs Under Section 501 a 5 of the FDCA T21 U.S.C. § 351(a)(5)!
The animal drugs that you compound from bulk active pharmaceutical ingredients (bulk APIs) are unsafe within the meaning of section 512 of the Act (21 U.S.C. § 360b) since they are not the subject of approved New Animal Drug Applications. Assuch, they are adulterated under section 501(a)(5) of the Act (21 U.S.C. § 351(a)(5)). Sections 512(a)(4) and (5) of the Act (21 U.S.C. §§ 360b(a)(4) and (5)), and their implementing regulations, allow some extralabel use of approved animal and human drugs, including compounding from approved animal and human drugs. These provisions, however, apply only to approved drugs and do not permit compounding from bulk APIs (see 21 C.F.R.§ 530.13(a)).'
4. Misbranded Drugs Under Section 502(o) of the FDCA 121 U.S.C. § 352(0)1
The human and animal drugs produced by your firm are misbranded under section 502(o) of the FDCA [21 U.S.C. § 352(o)] in that they are manufactured in an establishment not duly registered under section 510 of the FDCA [21 U.S.C. § 360], and the drugs have not been listed as required by section 510(j) ofthe FDCA [21 U.S.C. § 3600)]. Your facility is not exempt from registration and drug listing under section 510(g) of the FDCA [21 U.S.C. § 360(g)] or 21 C.F.R. § 207.10.
Wenote that it is also your responsibility to assure that you comply with current Good Manufacturing Practice (GMP) as delineated in 21 C.F.R. Parts 210 and 211. Future inspections will assess your compliance with these regulations.
F. Conclusion
The above violations are not intended to be an all-inclusive list of deficiencies. You

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Products Produced by The Compounding Shop Should B...

should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in additional regulatory action without further notice, including seizure of your products or injunction against you or your firm. Federal agencies are routinely advised of the issuance of warning letters so that they may take this information into account when considering the award of government contracts.
Please notify this office in writing within 15 working days of receipt of this letter of any steps you will take to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time frame within which the correction will be completed.
You should address your reply to this letter to the U.S. Food and Drug Administration, New Jersey District, 10Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Delia Fave, Compliance Officer.
Sincerely,
IS/
Douglas I. Ellsworth
District Director
New Jersey District
DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Silver Spring, MD 20993-0002
June 29, 2012
George J. Malmberg, R.Ph.
President and CEO
Wedgewood Pharmacy
405 Heron Drive #200
Swedesboro, NJ 08085
Dear Mr. Malmberg:
This letter concerns the information that appears on your website regarding Wedgewood Pharmacy's compounding of 17-hydroxyprogesterone caproate (HC). HC is the active ingredient in Makena, which, as you know, the Foodand Drug Administration (FDA) approved in February 2011 for the reduction of the risk of certain preterm births in women who have had at least one prior preterm birth.
Yourwebsite includes a press release Wedgewood Pharmacy issued on March 30, 2011, which interprets a statement issued by FDA the same day.' In the press release, titled "With FDAgreen light, Wedgewood Pharmacy continues to compound 17P (hydroxyprogesterone caproate)", Wedgewood Pharmacy acknowledged that"Under normal circumstances, compounding pharmacies muststop making a prescription drug when the same drug is manufactured as a commercial product." However, Wedgewood Pharmacy interpreted FDA's March 30, 2011, statement on Makena as "allowing] compounding pharmacies to continue" compounding hydroxyprogesterone caproate, and stated that it would"continue to prepare and dispense 1ml, 5ml and 10ml multi-dose vials of 17P (Hydroxyprogesterone Caproate)." Wedgewood Pharmacy's press statement also explained that"for patients with certain sensitivities, forwhom the use of Wedgewood Pharmacy's regular formulation of 17P is contraindicated, the company also will provide a preservative-free 17-alpha hydroxyprogesterone caproate, 250mg/ml, in single-dose vials." In addition, your website includes a statementtitled "FDA's Review of Compounded 17P Finds NoSafety or Purity Issues for Enforcement Policy Change," which states that "the FDA found no reason to change its enforcement policies regarding compounded Hydroxyprogesterone Caproate."
Weare writing to ensure that Wedgewood Pharmacy is not operating under the misimpression that there is a "green light" to compound large volumes of copies of Makena. On June 15, 2012, FDA updated the March 30, 2011, statement on compounded versions of hydroxyprogesterone caproate. That statement explained:
1http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm (March 30,2011).
Page 2
Compounding largevolumes of drugs that are copies of FDA-approved drugs circumvents important public health requirements, including the Federal Food, Drug, and Cosmetic Act's drug approval provisions.
Consumers and health professionals rely on the Act's evidence-based drug approval process to ensure that drugs are safeand effective. For that reason, one factor that the agency considers in determining whether a drug may be compounded is whether the prescribing practitioner has determined that a compounded product is necessary for the particular

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Law would make compounders subject to FDA oversigh...
Anh--New Draft of Compounding Pharmacy Bill Just R...
Drug consultant to St. Thomas clinic in meningitis...
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Senate pushes bill to regulate compound pharmacies...
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patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product. (emphasis added).

The statement also emphasized thatFDA is "applying its normal enforcement policies for compounded drugs to compounded hydroxyprogesterone caproate," and that the "compounding of any drug, including hydroxyprogesterone caproate, should not exceed the scope oftraditional pharmacy compounding." Acomplete copy ofthe statement is available on FDA's website at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm308546.htm.

As we explained in our October 31, 2006, Warning Letter to you, "[traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a massproduced product, ordiluted dosages for children." The information on your website indicates that you compound copies of the commercially available product as well as a preservative-free formulation for patients unable to tolerate the product that contains the preservative. You should be aware that FDA does not view compounding large volumes of drugs that are copies of FDA-approved drugs as traditional pharmacy compounding.

The compounding of copies of commercially available drugs is addressed in both section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353a) andthe Agency's compliance policy guide (CPG) on pharmacy compounding (CPG Sec. 460.200). For a drug to satisfy the conditions in section 503A, a pharmacist may "not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product." 21 U.S.C. §353a(b)(l)(D). Similarly, the CPG identifies factors that the Agency considers in deciding whether to initiate enforcement action with respect to compounding. One of the factors listed in the CPG is "Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved

2As you know, the Fifth and Ninth Circuit Courts of Appeals have reached different conclusions regarding whether section 503A is invalid or remains in effect. Compare Western States Med Or. v. Shalala, 238 F.3d 1090 (9th Cir. 2001) (holding that the solicitation and advertising prohibitions in section 503A are an impermissible regulation of commercial speech and that those provisions are unconstitutional and cannot be severed from the rest of section 503A, causing all of section 503Ato be invalid); with Medical Ctr. Pharm. v. Mukasey, 536 F.3d 383 (5th Cir. 2008) (compounded drugs are "new drugs" and "new animal drugs" within the meaning oftheAct and therefore are subject to regulation by the FDA, and the advertising prohibitions in section 503A previously found to be unconstitutional can be severed from section 503A, leaving the remaining parts of that section valid and effective).

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drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient." CPG Sec. 460.200 at 4-5.

As stated above, FDA does not consider compounding large volumes of copies, or what are essentially copies, of any approved commercially available drug to fall within the scope of traditional pharmacy practice. A Pharmacy that engages in such compounding may be subject to enforcement action.

CC:
Diana Amador Toro
Director, New Jersey District

Sincerely,
Kathleen R. Anderson, Pharm.D.
Director (acting), Office of Unapproved Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

at 5/19/2013 07:25:00 PM

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Health Reform Insider: Congress Dives Into SGR Ref...

Ruling thrills patients and boosts Indian generic ...

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Chemo IV drugs weren't properly labelled, firm say...

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Link to Feedback APIC Provided to Congress Re Draf...

APIC | APIC provides feedback on draft compounding...

Prescription Drug Info Blog: The Benefits Of Compo...

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Law 360 Says Compounding Bill May Hand FDA New Pow...

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Anesthesiology News - Doctor Group Claims Drug Pur...

FDA Law Blog Summary of Draft Compounding Legislat...

► April (382)

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Useful LINKS

Alliance for Safe Online Pharmacies

American Association of Equine Practitioners (AAEP)

American Society for Pharmacy Law

American Society of Health-System Pharmacists (ASHP) discussion guide on USP Chapter 797 for compounding sterile preparations

American Veterinary Medical Association (AVMA)

American Veterinary Medical Law Association

Animal Medicinal Drug Use

Essential and Historical Documents Related to Compounding

- November 14, 2012 – Written testimony of Dr. Margaret A. Hamburg, M.D. before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations hearing "The Fungal Meningitis Outbreak: Could It Have Been

Clarification Act of 1994 (AMDUCA)

Articles Addressing USP 797

CPG Sec. 608.400 Compounding of Drugs for Use in Animals

DEA, Diversion Control Pharmacists Manual

DEA, Office of Diversion Control

FDA Blog--FDA Voice

FDA Drug Shortages

FDA Modernization Act of 1997 (FDAMA)

Fifth Circuit - Medical Center Pharmacy v. Mukasey, 06-51583, July 18, 2008

Food and Drug Law Institute (FDLI)

Guidance for FDA Staff and Industry, Compliance Policy Guides Manual, Sec 460.200, Pharmacy Compounding(6/7/2002)

International Academy of Compounding Pharmacists

International Journal Pharmaceutical Compounding (IJPC)

National Association of Boards of Pharmacy

National Conference of State Legislation

PCCA

Section 127, Application of Federal Law to Practice of Pharmacy Compounding

State Laws and Rules on Compounding

Supreme Court Decision - Thompson et al. v. Western States Medical Center et al., U.S. Supreme Court Case No. 01-344, Decided April 29, 2002

U.S. Food and Drug Administration

U.S. Pharmacopeia

meningitis-etc by By Walter F. Roche Jr.

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- November 15, 2012 – Written testimony of Dr. Margaret A. Hamburg, M.D., before the Senate Committee on Health, Education, Labor and Pensions "Pharmacy Compounding: Implications ofthe 2012 Meningitis Outbreak".
- November 15, 2012 – Video of the Senate HELP Committee hearing.
- December 2012 - Transcript of FDA Meeting – "Framework for Pharmacy Compounding – State and Federal Roles"
- January 2013 – Comments Submitted to FDA Docket regarding "Framework for Pharmacy Compounding – State and Federal Roles"
- April 16, 2013 - Written testimony of Dr. Margaret A. Hamburg before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations – "Continuing Investigation into the Fungal Meningitis Outbreak: Could It

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Have Been Prevented?"

- April 16, 2013 – Video of testimony of Dr. Margaret A. Hamburg before the Energy and Commerce Committee.
- April 16, 2013 - House Energy and Commerce, Preliminary Majority Staff Report – "FDA's Oversight of NDCC and AmeriDose: A History of Missed Opportunities?"
- April 26, 2013 – Senate HELP Committee posts Draft Compounding Legislation, asks for public input by 5/2/13.
- May 23, 2013 – "Examining Drug Compounding" – Testimony given by Dr. Janet Woodcock, Director CDER before the House Subcommittee on Health , Committee of Energy and Commerce.
- July 16, 2013 – "Reforming the Drug Compounding Regulatory Framework" – Statement given by Dr. Janet Woodcock, Director CDER before the House Subcommittee on Health, Committee of Energy and Commerce.
- July 31, 2013 – GAO Report – "Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA

Oversight"

- November 18, 2013 - Drug Quality and Security Act passes Senate on voice vote – passed House in September – goes to President Obama for signature.
- Bulk Drug Substances that May be Used to Compound Drug Products, etc., Concerning Outsourcing Facilities: Request for Nominations
- Draft Guidance for Industry and Staff: Interim Product Reporting for Human Drug Compounding Outsourcing Facilities under the Federal Food, Drug, and Cosmetic Act
- Draft Guidance for Industry and Staff: Pharmacy Compounding of Human Drug Products under the Federal Food, Drug, and Cosmetic Act; Availability; Withdrawal
- Draft Guidance for Industry and Staff: Registration for Human Drug Compounding Outsourcing Facilities under the Federal Food, Drug, and Cosmetic Act
- Drug Products that Present Demonstrable Difficulties for Compounding: Request for Nominations
- List of Bulk Drug

- List of Bulk Drug Substances that May be Used in Pharmacy Compounding; Withdrawal

Other Publications

Author, Joint Defense Agreements: Could It Help Your Client, Oklahoma Bar Journal, March 1998

Author, King for a Day, An Overview of Qui Tam Litigation Under State and Federal Law, Oklahoma Bar Journal, May 1999

Author, The Fifth Amendment Privilege Against Self-Incrimination: Walking the Tight Rope in Parallel Civil and Criminal Proceedings, Oklahoma Bar Association, October 2002

Tenth Circuit Standards of Review Manual, Western District of Oklahoma

Criminal Appeals Manual, Western District of Oklahoma

Creator, Author, and Presentor of Year in Review for Department of Justice United States Attorney's Office, Western District of Oklahoma

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EXHIBIT I

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EXHIBIT J

Table C-1.
U.S. District Courts—Civil Cases Commenced, Terminated, and Pending During the 12-Month Period Ending March 31, 2014

Circuit and District	Total Civil Cases				U.S. Civil Cases				Private Civil Cases			
	Pending Mar. 31, 2013 [1]	Commenced	Terminated	Pending Mar. 31, 2014	Pending Mar. 31, 2013 [1]	Commenced	Terminated	Pending Mar. 31, 2014	Pending Mar. 31, 2013 [1]	Commenced	Terminated	Pending Mar. 31, 2014
TOTAL	**280,575**	**303,820**	**260,840**	**323,555**	**44,476**	**46,727**	**46,304**	**44,899**	**236,099**	**257,093**	**214,536**	**278,656**
DC	**2,212**	**2,218**	**2,103**	**2,327**	**1,128**	**1,069**	**1,024**	**1,173**	**1,084**	**1,149**	**1,079**	**1,154**
1ST	**8,637**	**7,469**	**6,969**	**9,137**	**1,234**	**1,272**	**1,129**	**1,377**	**7,403**	**6,197**	**5,840**	**7,760**
ME	341	502	420	423	110	197	149	158	231	305	271	265
MA	3,245	4,599	2,884	4,960	548	591	471	668	2,697	4,008	2,413	4,292
NH	509	520	558	471	126	158	147	137	383	362	411	334
RI	3,134	880	2,041	1,973	77	94	77	94	3,057	786	1,964	1,879
PR	1,408	968	1,066	1,310	373	232	285	320	1,035	736	781	990
2ND	**28,207**	**23,713**	**21,874**	**30,046**	**3,668**	**3,618**	**3,228**	**4,058**	**24,539**	**20,095**	**18,646**	**25,988**
CT	2,356	1,986	2,022	2,320	372	378	336	414	1,984	1,608	1,686	1,906
NY,N	2,110	1,729	1,775	2,064	555	487	479	563	1,555	1,242	1,296	1,501
NY,E	7,852	7,870	6,285	9,437	1,013	1,018	943	1,088	6,839	6,852	5,342	8,349
NY,S	13,292	9,941	9,683	13,550	1,063	1,030	918	1,175	12,229	8,911	8,765	12,375
NY,W	2,329	1,851	1,778	2,402	602	589	470	721	1,727	1,262	1,308	1,681
VT	268	336	331	273	63	116	82	97	205	220	249	176
3RD	**28,108**	**27,654**	**30,461**	**25,301**	**3,020**	**3,938**	**3,894**	**3,064**	**25,088**	**23,716**	**26,567**	**22,237**
DE	2,444	2,111	1,991	2,564	143	67	79	131	2,301	2,044	1,912	2,433
NJ	7,416	8,583	8,154	7,845	856	1,171	1,083	944	6,560	7,412	7,071	6,901
PA,E	12,958	11,061	14,193	9,826	676	932	902	706	12,282	10,129	13,291	9,120
PA,M	2,774	3,003	3,062	2,715	821	1,171	1,205	787	1,953	1,832	1,857	1,928
PA,W	2,022	2,665	2,775	1,912	444	569	576	437	1,578	2,096	2,199	1,475
VI	494	231	286	439	80	28	49	59	414	203	237	380
4TH	**32,231**	**58,594**	**18,843**	**71,982**	**5,676**	**4,464**	**4,787**	**5,353**	**26,555**	**54,130**	**14,056**	**66,629**
MD	3,071	4,043	3,925	3,189	803	822	894	731	2,268	3,221	3,031	2,458
NC,E	2,234	2,016	2,140	2,110	1,127	840	971	996	1,107	1,176	1,169	1,114
NC,M	1,726	1,175	1,360	1,541	911	357	409	859	815	818	951	682
NC,W	1,290	1,149	1,320	1,119	483	367	443	407	807	782	877	712
SC	3,125	3,995	3,493	3,627	752	690	670	772	2,373	3,305	2,823	2,855
VA,E	1,952	3,322	3,322	1,952	536	603	674	465	1,416	2,719	2,648	1,487
VA,W	720	1,187	1,198	709	285	390	394	281	435	797	804	428
WV,N	603	655	602	656	119	163	145	137	484	492	457	519
WV,S	17,510	41,052	1,483	57,079	660	232	187	705	16,850	40,820	1,296	56,374

EXHIBIT
A000202

Table C-1. (March 31, 2014—Continued)

Circuit and District	Total Civil Cases				U.S. Civil Cases				Private Civil Cases			
	Pending Mar. 31, 2013 [1]	Commenced	Terminated	Pending Mar. 31, 2014	Pending Mar. 31, 2013 [1]	Commenced	Terminated	Pending Mar. 31, 2014	Pending Mar. 31, 2013 [1]	Commenced	Terminated	Pending Mar. 31, 2014
5TH	**29,289**	**33,678**	**28,122**	**34,845**	**4,087**	**3,751**	**4,141**	**3,697**	**25,202**	**29,927**	**23,981**	**31,148**
LA,E	3,858	6,589	4,212	6,235	385	321	443	263	3,473	6,268	3,769	5,972
LA,M	879	863	858	884	108	91	106	93	771	772	752	791
LA,W	3,514	3,369	1,932	4,951	356	333	316	373	3,158	3,036	1,616	4,578
MS,N	831	793	905	719	131	113	139	105	700	680	766	614
MS,S	1,879	2,053	2,072	1,860	242	197	210	229	1,637	1,856	1,862	1,631
TX,N	7,463	6,763	4,920	9,306	718	774	942	550	6,745	5,989	3,978	8,756
TX,E	3,802	4,052	4,060	3,794	621	480	505	596	3,181	3,572	3,555	3,198
TX,S	4,647	5,879	5,774	4,752	903	770	769	904	3,744	5,109	5,005	3,848
TX,W	2,416	3,317	3,389	2,344	623	672	711	584	1,793	2,645	2,678	1,760
6TH	**28,122**	**22,653**	**21,393**	**29,382**	**4,113**	**4,781**	**4,034**	**4,860**	**24,009**	**17,872**	**17,359**	**24,522**
KY,E	1,240	1,513	1,333	1,420	370	670	433	607	870	843	900	813
KY,W	1,465	1,778	1,279	1,964	198	250	263	185	1,267	1,528	1,016	1,779
MI,E	5,644	5,283	5,517	5,410	1,000	1,155	1,019	1,136	4,644	4,128	4,498	4,274
MI,W	1,469	1,737	1,757	1,449	238	333	271	300	1,231	1,404	1,486	1,149
OH,N	10,224	4,248	3,277	11,195	604	783	729	658	9,620	3,465	2,548	10,537
OH,S	2,599	2,715	2,637	2,677	588	660	611	637	2,011	2,055	2,026	2,040
TN,E	1,902	1,560	1,613	1,849	438	328	286	480	1,464	1,232	1,327	1,369
TN,M	1,903	2,441	2,555	1,789	305	295	215	385	1,598	2,146	2,340	1,404
TN,W	1,676	1,378	1,425	1,629	372	307	207	472	1,304	1,071	1,218	1,157
7TH	**29,565**	**23,316**	**20,683**	**32,198**	**3,009**	**2,833**	**2,874**	**2,968**	**26,556**	**20,483**	**17,809**	**29,230**
IL,N	10,326	9,735	9,568	10,493	1,237	1,068	1,026	1,279	9,089	8,667	8,542	9,214
IL,C	1,462	1,447	1,381	1,528	271	199	229	241	1,191	1,248	1,152	1,287
IL,S	11,618	4,015	2,735	12,898	262	307	311	258	11,356	3,708	2,424	12,640
IN,N	1,992	2,814	1,735	3,071	368	327	360	335	1,624	2,487	1,375	2,736
IN,S	2,374	2,838	2,898	2,314	474	494	488	480	1,900	2,344	2,410	1,834
WI,E	1,062	1,520	1,443	1,139	204	248	255	197	858	1,272	1,188	942
WI,W	731	947	923	755	193	190	205	178	538	757	718	577
8TH	**18,236**	**14,431**	**18,910**	**13,757**	**3,686**	**3,515**	**3,986**	**3,215**	**14,550**	**10,916**	**14,924**	**10,542**
AR,E	5,179	1,793	5,302	1,670	570	417	582	405	4,609	1,376	4,720	1,265
AR,W	1,173	1,113	1,135	1,151	649	506	602	553	524	607	533	598
IA,N	426	515	540	401	183	278	282	179	243	237	258	222
IA,S	610	641	708	543	164	213	217	160	446	428	491	383
MN	4,041	3,775	4,684	3,132	238	355	327	266	3,803	3,420	4,357	2,866
MO,E	3,423	3,028	2,718	3,733	622	524	636	510	2,801	2,504	2,082	3,223
MO,W	2,045	2,377	2,533	1,889	946	950	1,014	882	1,099	1,427	1,519	1,007
NE	597	614	647	564	124	137	153	108	473	477	494	456
ND	329	283	324	288	66	56	71	51	263	227	253	237
SD	413	292	319	386	124	79	102	101	289	213	217	285

Table C-1. (March 31, 2014—Continued)

Circuit and District	Total Civil Cases				U.S. Civil Cases				Private Civil Cases			
	Pending Mar. 31, 2013 [1]	Commenced	Terminated	Pending Mar. 31, 2014	Pending Mar. 31, 2013 [1]	Commenced	Terminated	Pending Mar. 31, 2014	Pending Mar. 31, 2013 [1]	Commenced	Terminated	Pending Mar. 31, 2014
9TH	**38,970**	**48,355**	**46,682**	**40,643**	**7,484**	**9,358**	**9,053**	**7,789**	**31,486**	**38,997**	**37,629**	**32,854**
AK	326	307	321	312	104	111	97	118	222	196	224	194
AZ	2,934	7,461	5,030	5,365	788	1,124	1,085	827	2,146	6,337	3,945	4,538
CA,N	5,810	6,179	6,482	5,507	560	630	619	571	5,250	5,549	5,863	4,936
CA,E	5,608	4,882	4,851	5,639	847	900	806	941	4,761	3,982	4,045	4,698
CA,C	10,618	14,384	14,783	10,219	2,002	3,100	2,976	2,126	8,616	11,284	11,807	8,093
CA,S	2,887	3,491	3,279	3,099	516	408	530	394	2,371	3,083	2,749	2,705
HI	624	750	796	578	93	114	117	90	531	636	679	488
ID	743	536	610	669	144	104	105	143	599	432	505	526
MT	554	755	719	590	141	162	143	160	413	593	576	430
NV	3,163	2,978	2,813	3,328	356	353	268	441	2,807	2,625	2,545	2,887
OR	2,320	2,315	2,385	2,250	744	765	696	813	1,576	1,550	1,689	1,437
WA,E	938	782	1,048	672	452	377	501	328	486	405	547	344
WA,W	2,310	3,481	3,493	2,298	701	1,203	1,095	809	1,609	2,278	2,398	1,489
GUAM	67	22	38	51	25	3	11	17	42	19	27	34
NMI	68	32	34	66	11	4	4	11	57	28	30	55
10TH	**9,176**	**10,736**	**10,416**	**9,496**	**2,171**	**2,393**	**2,234**	**2,330**	**7,005**	**8,343**	**8,182**	**7,166**
CO	2,367	3,626	3,331	2,662	410	437	399	448	1,957	3,189	2,932	2,214
KS	1,423	1,458	1,530	1,351	423	441	480	384	1,000	1,017	1,050	967
NM	1,242	1,267	1,190	1,319	301	325	281	345	941	942	909	974
OK,N	744	821	799	766	219	316	257	278	525	505	542	488
OK,E	510	548	558	500	237	259	229	267	273	289	329	233
OK,W	1,040	1,433	1,373	1,100	226	376	307	295	814	1,057	1,066	805
UT	1,595	1,298	1,348	1,545	303	192	221	274	1,292	1,106	1,127	1,271
WY	255	285	287	253	52	47	60	39	203	238	227	214
11TH	**27,822**	**31,003**	**34,384**	**24,441**	**5,200**	**5,735**	**5,920**	**5,015**	**22,622**	**25,268**	**28,464**	**19,426**
AL,N	6,000	2,433	5,556	2,877	714	558	617	655	5,286	1,875	4,939	2,222
AL,M	1,161	1,022	1,117	1,066	235	191	212	214	926	831	905	852
AL,S	599	658	759	498	175	137	181	131	424	521	578	367
FL,N	1,622	2,011	2,083	1,550	440	388	461	367	1,182	1,623	1,622	1,183
FL,M	7,986	8,501	9,079	7,408	1,727	1,936	1,965	1,698	6,259	6,565	7,114	5,710
FL,S	4,765	8,618	8,370	5,013	898	1,264	1,309	853	3,867	7,354	7,061	4,160
GA,N	3,791	5,101	5,110	3,782	638	718	714	642	3,153	4,383	4,396	3,140
GA,M	1,171	1,594	1,334	1,431	220	263	245	238	951	1,331	1,089	1,193
GA,S	727	1,065	976	816	153	280	216	217	574	785	760	599

NOTE: Includes cases filed in previous years as consolidated cases that thereafter were severed into individual cases.
[1] Revised.

EXHIBIT K

Table C-5.
U.S. District Courts—Median Time Intervals From Filing to Disposition of Civil Cases Terminated, by District and Method of Disposition, During the 12-Month Period Ending March 31, 2014

Circuit and District	Total Cases		No Court Action		Court Action					
					Before Pretrial		During or After Pretrial		Trial	
	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months
TOTAL	**199,787**	**8.6**	**43,141**	**5.0**	**127,635**	**8.6**	**26,306**	**12.7**	**2,705**	**24.4**
DC	**1,748**	**7.9**	**818**	**5.4**	**886**	**9.8**	**9**	**-**	**35**	**31.0**
1ST	**6,311**	**12.8**	**1,127**	**3.6**	**3,684**	**15.5**	**1,404**	**14.8**	**96**	**27.3**
ME	356	7.9	151	5.5	188	9.3	11	14.5	6	-
MA	2,563	9.0	638	2.6	772	7.5	1,099	14.4	54	27.6
NH	471	8.6	75	2.9	208	6.7	181	15.1	7	-
RI	1,988	36.8	97	8.6	1,840	38.4	37	19.5	14	33.1
PR	933	13.0	166	7.5	676	13.4	76	19.0	15	21.6
2ND	**18,289**	**8.7**	**3,278**	**4.8**	**10,477**	**8.3**	**4,198**	**12.0**	**336**	**31.9**
CT	1,734	9.7	700	6.2	672	10.0	318	17.3	44	34.5
NY,N	1,171	11.0	230	3.4	575	12.7	339	14.4	27	34.7
NY,E	5,601	8.6	1,220	5.6	3,121	8.2	1,163	11.9	97	30.9
NY,S	8,310	8.1	897	3.5	4,941	7.1	2,318	11.3	154	31.5
NY,W	1,262	9.4	204	3.6	994	10.8	55	29.8	9	-
VT	211	9.5	27	4.3	174	9.6	5	-	5	-
3RD	**23,793**	**8.1**	**2,778**	**3.9**	**16,506**	**7.0**	**4,259**	**13.5**	**250**	**26.7**
DE	1,759	7.7	680	5.0	928	9.0	116	13.6	35	31.4
NJ	6,766	7.5	400	3.0	3,605	4.1	2,714	16.6	47	36.8
PA,E	11,464	8.7	812	3.6	9,313	9.1	1,239	9.3	100	16.7
PA,M	1,596	8.1	412	5.0	1,054	8.7	100	16.0	30	26.7
PA,W	1,939	7.2	309	3.0	1,584	8.1	21	24.3	25	27.0
VI	269	15.6	165	13.1	22	20.0	69	18.1	13	45.9
4TH	**12,561**	**7.6**	**2,179**	**6.0**	**8,857**	**7.4**	**1,343**	**9.9**	**182**	**20.1**
MD	2,975	7.6	429	7.3	1,923	5.9	582	12.0	41	22.7
NC,E	1,226	8.5	332	8.0	887	8.6	3	-	4	-
NC,M	698	10.9	432	8.5	219	14.5	38	25.1	9	-
NC,W	868	9.1	222	6.7	545	9.1	88	12.1	13	24.3
SC	2,203	9.4	195	3.2	1,918	10.0	57	9.9	33	25.5
VA,E	2,203	5.5	331	4.3	1,311	4.5	508	7.3	53	11.9
VA,W	680	8.5	167	4.0	445	9.4	55	9.4	13	15.0
WV,N	378	9.0	50	4.4	320	9.4	3	-	5	-
WV,S	1,330	6.2	21	6.6	1,289	6.2	9	-	11	23.7

Table C-5. (March 31, 2014—Continued)

Circuit and District	Total Cases		No Court Action		Court Action					
					Before Pretrial		During or After Pretrial		Trial	
	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months
5TH	**20,750**	**7.5**	**5,535**	**5.0**	**12,712**	**7.5**	**2,151**	**11.4**	**352**	**23.1**
LA,E	3,728	4.9	112	1.8	2,493	4.7	1,057	10.4	66	20.5
LA,M	621	12.2	127	9.3	451	11.9	34	26.1	9	-
LA,W	1,133	11.5	408	7.5	654	12.8	44	21.1	27	30.8
MS,N	696	9.8	206	7.6	288	8.2	186	14.3	16	19.5
MS,S	1,454	9.7	805	6.6	585	11.0	38	19.8	26	26.4
TX,N	3,322	6.4	661	4.3	2,619	6.9	1	-	41	22.8
TX,E	2,956	9.1	830	5.0	2,015	10.0	58	19.0	53	26.1
TX,S	4,426	6.8	1,657	4.2	2,054	7.8	642	9.2	73	19.7
TX,W	2,414	6.9	729	5.6	1,553	6.8	91	15.3	41	21.6
6TH	**15,991**	**9.2**	**4,921**	**5.7**	**7,227**	**8.8**	**3,642**	**12.5**	**201**	**26.8**
KY,E	954	9.0	124	5.4	795	9.1	23	20.0	12	35.4
KY,W	1,030	8.2	172	5.5	804	8.2	43	16.8	11	27.2
MI,E	4,273	8.4	985	3.3	1,443	5.8	1,807	12.9	38	27.2
MI,W	998	8.3	184	2.2	515	8.0	288	12.3	11	29.8
OH,N	2,771	8.5	868	4.6	1,107	10.7	760	10.1	36	16.9
OH,S	2,277	9.6	1,036	6.0	602	11.8	609	12.6	30	29.4
TN,E	1,264	11.3	597	9.0	555	11.9	90	17.1	22	25.6
TN,M	1,432	11.9	341	24.4	1,057	9.8	7	-	27	28.0
TN,W	992	11.2	614	11.7	349	9.5	15	22.9	14	22.8
7TH	**16,080**	**8.6**	**3,945**	**5.0**	**9,773**	**8.8**	**2,192**	**12.3**	**170**	**27.3**
IL,N	8,154	6.8	2,189	5.1	5,294	7.0	578	11.1	93	31.2
IL,C	778	9.6	355	5.3	409	12.6	1	-	13	29.4
IL,S	2,133	18.7	527	16.8	1,586	19.2	4	-	16	19.0
IN,N	1,351	11.0	231	2.8	569	9.8	537	15.4	14	26.1
IN,S	1,957	8.9	263	3.7	875	7.4	805	11.6	14	27.1
WI,E	1,064	6.1	244	3.1	789	7.2	23	8.5	8	-
WI,W	643	7.5	136	3.1	251	6.0	244	11.1	12	15.2
8TH	**15,850**	**14.1**	**5,511**	**9.6**	**9,081**	**15.7**	**1,074**	**13.5**	**184**	**22.5**
AR,E	4,565	59.6	1,684	61.1	2,838	59.2	4	-	39	18.4
AR,W	901	12.5	138	12.4	756	12.4	0	-	7	-
IA,N	388	8.6	69	8.4	309	8.6	2	-	8	-
IA,S	481	9.6	99	6.0	214	7.4	153	14.8	15	25.2
MN	4,430	12.6	1,403	1.7	2,207	27.0	792	13.0	28	23.0
MO,E	2,173	8.5	1,030	5.6	1,105	10.9	6	-	32	22.6
MO,W	1,951	10.5	944	7.6	891	12.8	98	12.7	18	23.3
NE	496	9.0	54	2.2	411	9.4	9	-	22	22.4
ND	237	13.5	7	-	222	13.2	4	-	4	-
SD	228	14.3	83	11.7	128	14.5	6	-	11	30.9

Table C-5. (March 31, 2014—Continued)

Circuit and District	Total Cases		No Court Action		Court Action					
					Before Pretrial		During or After Pretrial		Trial	
	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months
9TH	**33,582**	**7.4**	**8,725**	**4.3**	**21,025**	**7.7**	**3,377**	**13.3**	**455**	**24.1**
AK	249	9.2	35	5.2	210	10.5	0	-	4	-
AZ	2,439	7.7	128	2.3	1,679	6.4	584	13.5	48	29.2
CA,N	4,979	8.1	984	4.4	2,478	7.0	1,459	12.3	58	28.4
CA,E	2,577	8.8	880	5.7	1,618	10.4	50	19.0	29	31.5
CA,C	11,560	5.8	4,073	4.3	7,130	6.6	211	14.2	146	21.4
CA,S	2,345	6.6	385	3.3	1,224	5.3	711	13.2	25	27.0
HI	696	7.2	348	4.8	292	8.3	42	23.7	14	14.5
ID	392	11.6	32	1.9	277	10.8	72	16.7	11	23.6
MT	435	9.2	142	4.6	152	7.4	129	14.1	12	19.1
NV	2,143	8.9	265	3.9	1,776	9.8	86	8.6	16	41.5
OR	1,926	11.3	502	8.6	1,375	11.6	8	-	41	22.5
WA,E	865	13.0	262	5.4	586	14.8	6	-	11	24.1
WA,W	2,917	6.7	657	2.3	2,210	7.5	10	20.2	40	18.7
GUAM	29	23.2	7	-	13	28.9	9	-	0	-
NMI	30	14.9	25	14.0	5	-	0	-	0	-
10TH	**8,503**	**8.8**	**2,114**	**4.6**	**5,203**	**9.2**	**1,042**	**13.7**	**144**	**24.7**
CO	2,658	6.2	905	4.4	1,630	6.6	81	18.4	42	27.2
KS	1,246	8.6	339	4.8	787	9.0	103	17.8	17	24.6
NM	998	10.3	259	6.5	412	10.7	306	12.9	21	26.9
OK,N	663	9.6	66	3.1	573	10.2	17	18.2	7	-
OK,E	428	13.7	20	2.5	394	14.0	7	-	7	-
OK,W	1,089	8.5	251	4.1	469	8.0	347	10.8	22	18.2
UT	1,204	11.6	208	5.4	880	12.4	94	22.8	22	36.4
WY	217	9.6	66	3.6	58	8.4	87	13.2	6	-
11TH	**26,329**	**8.0**	**2,210**	**4.0**	**22,204**	**8.1**	**1,615**	**12.2**	**300**	**20.5**
AL,N	4,906	22.7	48	2.0	4,808	22.7	22	30.2	28	21.7
AL,M	728	9.8	71	4.4	605	9.6	41	17.7	11	24.9
AL,S	535	8.1	117	3.8	396	8.5	16	16.3	6	-
FL,N	1,357	6.7	61	3.3	1,275	6.9	10	22.3	11	24.5
FL,M	6,748	8.3	509	6.2	6,034	8.1	112	17.4	93	21.4
FL,S	6,717	4.7	626	3.2	5,943	4.8	57	11.5	91	16.1
GA,N	4,055	6.7	363	2.6	2,318	4.8	1,339	11.2	35	28.1
GA,M	775	9.8	230	5.8	523	11.0	3	-	19	25.1
GA,S	508	8.9	185	6.9	302	10.1	15	19.7	6	-

NOTE: Median time intervals are not computed when fewer than 10 cases reported. This table excludes land condemnations, prisoner petitions, deportation reviews, recovery of overpayments, and enforcement of judgments. Includes cases filed in previous years as consolidated cases that thereafter were severed into individual cases. For fiscal years prior to 2001, this table included data on recovery of overpayments and enforcement of judgments.

EXHIBIT L

<< Workloads for Federal Judges Up, Judge Counts Flat

Table 2. Variation in Judge Caseloads Among Districts
(for the 12 Month Period ending June 30, 2014)

(Click column header to sort)

Judicial District	Weighted Filings per Full-Time Equivalent Judge*			Ranks		
	Civil	Criminal	Combined	Civil	Criminal	Combined
US Average	303	85	388			
Ala, M	309	71	380	27	40	29
Ala, N	224	46	270	51	66	62
Ala, S	162	103	265	74	26	65
Alaska	80	64	145	90	50	91
Arizona	379	347	725	14	2	3
Ark, E	244	70	314	42	43	41
Ark, W	183	71	254	66	40	72
Cal, C	477	28	505	8	84	15
Cal, E	527	111	638	3	22	5
Cal, N	270	41	311	32	74	42
Cal, S	264	259	523	36	5	13
Colorado	291	63	355	30	53	34
Conn	242	57	299	43	54	47
D. C.	153	17	171	76	91	86
Delaware	1423	23	1446	1	89	2
Fla, M	459	71	530	9	40	11
Fla, N	348	54	402	18	57	25
Fla, S	523	144	667	5	13	4
Ga, M	228	83	310	49	32	43
Ga, N	425	44	469	11	68	17
Ga, S	242	28	270	43	84	62
Hawaii	153	88	241	76	31	80
Idaho	179	127	306	67	16	45
Ill, C	231	51	282	48	59	57
Ill, N	358	31	389	16	82	26
Ill, S	363	124	487	15	17	16
Ind, N	188	50	238	63	62	81
Ind, S	522	66	587	6	48	7
Iowa, N	111	168	279	83	8	58
Iowa, S	128	27	156	80	86	89
Kansas	156	188	345	75	7	36
Ken, E	164	108	271	73	24	61

EXHIBIT

A000210

Ken, W	331	81	412	21	37	23
La, E	225	30	256	50	83	70
La, M	256	42	298	38	72	48
La, W	167	26	193	72	88	83
Maine	102	44	146	85	68	90
Maryland	314	65	379	26	49	30
Mass	254	35	289	40	79	54
Mich, E	208	46	255	56	66	71
Mich, W	297	81	378	28	37	31
Minnesota	357	32	389	17	80	26
Miss, N	202	44	246	58	68	78
Miss, S	254	49	303	40	64	46
Mo, E	202	92	294	59	29	51
Mo, W	192	115	307	60	20	44
Montana	237	151	388	46	11	28
N Car, E	327	128	455	22	15	19
N Car, M	210	42	253	55	72	74
N Car, W	186	133	319	64	14	38
N Dakota	101	161	262	86	9	66
N Mexico	111	256	367	83	6	33
N. J.	491	38	529	7	77	12
N. Y., E	392	38	431	13	77	21
N. Y., N	268	51	318	34	59	39
N. Y., S	294	39	332	29	75	37
N. Y., W	316	95	412	25	27	23
Nebraska	140	114	254	79	21	73
Nevada	457	51	508	10	59	14
New Hamp	125	43	168	81	71	87
Ohio, N	222	64	286	52	50	55
Ohio, S	239	47	286	45	65	55
Okla, E	192	55	247	60	55	77
Okla, N	179	67	246	67	46	78
Okla, W	205	54	260	57	57	67
Oregon	178	70	248	69	43	76
Penn, E	259	32	291	37	80	53
Penn, M	269	27	296	33	86	50
Penn, W	235	39	273	47	75	60
Puerto Rico	91	348	439	89	1	20
R. I.	189	69	258	62	45	69
S Car	277	20	297	31	90	49
S Dakota	73	90	163	91	30	88
Tenn, E	340	121	461	20	18	18

Tenn, M	523	50	573	4	62	9
Tenn, W	148	111	259	78	22	68
Texas, E	1350	161	1510	2	9	1
Texas, N	416	116	532	12	19	10
Texas, S	318	268	586	23	4	8
Texas, W	267	330	597	35	3	6
Utah	184	83	267	65	32	64
Vermont	93	82	175	88	35	85
Virg, E	219	73	292	53	39	52
Virg, W	169	82	251	71	35	75
W Virg, N	171	147	318	70	12	39
W Virg, S	212	64	276	54	50	59
Wash, E	117	108	225	82	24	82
Wash, W	317	55	372	24	55	32
Wisc, E	255	94	348	39	28	35
Wisc, W	346	67	413	19	46	22
Wyoming	99	83	182	87	32	84

** See Civil Cases in District Court: About the Data for further details on how these indices were developed.*

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

EATON VETERINARY PHARMACEUTICAL, INC.,	)	
Plaintiff,	)	
v.	)	Case No. 4:15-cv-00687-SRB
WEDGEWOOD VILLAGE PHARMACY, INC.,	)	
Defendant.	)	

JOINTLY PROPOSED SCHEDULING ORDER AND DISCOVERY PLAN

Pursuant to Rule 16(b) of the Federal Rules of Civil Procedure and Local Rule 16.1 of the United States District Court for the Western District of Missouri, the parties conducted a party planning meeting on November 23, 2015 and submit the following proposed scheduling order and discovery plan.

1. Trial Setting

The parties request a jury trial setting beginning May 22, 2017, as it fits with the Court's schedule and anticipate that the case will take one week to try.

2. Pleadings

a. Any motion to join additional parties: January 15, 2016

b. Any motion to amend the pleadings: January 15, 2016

3. Discovery Plan

a. All fact depositions and written fact discovery will be completed by July 1, 2016. The parties will be substantially complete with document production by April 15, 2016. Fact discovery motions shall be filed on or before June 15, 2016. The parties recognize their need to follow the procedures of Local Rule 37.1 before filing discovery motions.

b. Expert designations and depositions will be as follows:

(1) On or before August 4, 2016, the party bearing the burden of proof on any issues shall designate and serve on the opposing party a report for any expert witnesses it intends to call at trial. Plaintiff's opening expert reports will include any secondary considerations of nonobviousness on which it intends to rely in opposition to obviousness contentions from Defendant. This does not alter the ultimate burden of proof of invalidity.

(3) On or before September 15, 2016, rebuttal experts shall be designated and report(s) shall be served on the opposing party.

(5) On or before November 18, 2016, all depositions of expert witnesses and all other expert discovery shall be completed.

c. Counsel considered the complexity of the issues and the number of parties in this case in determining the proposed discovery deadline. Plaintiff's claims (and alleged damages), Defendant's affirmative defenses and counterclaims (and alleged damages). No discovery has been conducted to date. The parties anticipate serving interrogatories and document requests and taking depositions of lay and expert witnesses.

Eaton proposes that discovery does not need to be conducted in phases or be limited to or focused upon particular issues. Wedgewood proposes severing the issues of liability from damages, and accordingly conducting discovery and trial on liability issues first, followed by a period of discovery and a trial on damages only as necessary.

d. The parties will exchange Rule 26 initial disclosures by December 18, 2015.

e. The parties request a maximum of 10 fact depositions for Plaintiff and a maximum of 10 fact depositions for Defendant. Requests for additional depositions require leave of the Court. Each party may serve a Rule 30(b)(6) notice, which will count as one deposition for purposes of the limit of ten depositions. Each party may serve up to 25 individual interrogatories on the other party. There are no limits to Requests for Production or Requests for Admission as long as the number and scope of requests are not unreasonable or unduly burdensome.

f. The parties anticipate requesting a protective order. The parties will confer and jointly propose a protective order for the Court to enter which would protect individual privacy concerns and proprietary information of the parties. The parties will submit their jointly proposed order to the Court as soon as possible. If the parties cannot agree on the terms of a proposed order, they will each separately submit proposed orders for the Court's consideration by January 7, 2015.

4. Dates for Filing Dispositive Motions

All dispositive motions, except those under 12(h)(2) or (3) will be filed on or before December 16, 2016. All summary judgment motions will comply with Local Rule

56.1 and will be filed no later than December 16, 2016. Any Daubert motions will be filed no later than December 16, 2016.

5. ADR

Plaintiff shall send a settlement offer to Defendant on or before January 14, 2016. Defendant shall send a counter offer to Plaintiff on or before February 25, 2016. The Court has scheduled mediation for this case on March 2, 2016.

6. ESI

The parties propose conducting e-discovery as outlined in proposed stipulation attached as Exhibit A.

7. Patent Disclosures

a. Disclosure of Asserted Claims and Infringement Contentions: Not later than January 29, 2016, Plaintiff shall serve on Defendant a "Disclosure of Asserted Claims and Infringement Contentions." The "Disclosure of Asserted Claims and Infringement Contentions" shall contain the following information:

(1) Each claim of each patent in suit that is allegedly infringed;

(2) Each accused process, method, act, or other instrumentality ("Accused Method");

(3) A chart identifying specifically where each element of each asserted claim is found within each Accused Method, including for each element that such party contends is governed by 35 U.S.C. § 112(6),

the identity of the structure(s), act(s), or material(s) in the Accused Method that performs the claimed function;

(4) Whether each element of each asserted claim is claimed to be literally present or present under the doctrine of equivalents in the Accused Method; and

(5) For any patent that claims priority to an earlier application, the priority date to which each asserted claim allegedly is entitled.

b. Document Production Accompanying Disclosure: With the "Disclosure of Asserted Claims and Infringement Contentions," Plaintiff shall produce:

(1) Documents (e.g., contracts, purchase orders, invoices, advertisements, marketing materials, offer letters, beta site testing agreements, and third party or joint development agreements) sufficient to evidence each discussion with, disclosure to, or other manner of providing to a third party, or sale of or offer to sell, the claimed invention prior to the date of application for the patent in suit. A party's production of a document as required herein shall not constitute an admission that such document evidences or is prior art under 35 U.S.C. § 102;

(2) All documents evidencing the conception, reduction to practice, design, and development of each claimed invention, which were created on or before the date of application for the patent in suit or

the priority date identified pursuant to ¶ 7.a.(5), whichever is earlier; and

(3) A copy of the file history for each patent in suit.

c. Invalidity Contentions: Not later than March11, 2016, Defendant shall serve their "Invalidity Contentions" which must contain the following information:

(1) The identity of each item of prior art that allegedly anticipates each asserted claim or renders it obvious. Each prior art patent shall be identified by its number, country of origin, and date of issue. Each prior art publication must be identified by its title, date of publication, and where feasible, author and publisher. Prior art under 35 U.S.C. § 102(b) shall be identified by specifying the item offered for sale or publicly used or known, the date the offer or use took place or the information became known, and the identity of the person or entity which made the use or which made and received the offer, or the person or entity which made the information known or to whom it was made known. Prior art under 35 U.S.C. § 102(f) shall be identified by providing the name of the person(s) from whom and the circumstances under which the invention or any part of it was derived. Prior art under 35 U.S.C. § 102(g) shall be identified by providing the identities of the person(s) or entities

involved in and the circumstances surrounding the making of the invention before the patent applicant(s);

(2) Whether each item of prior art anticipates each asserted claim or renders it obvious. If a combination of items of prior art makes a claim obvious, each such combination, and the motivation to combine such items, must be identified;

(3) A chart identifying where specifically in each alleged item of prior art each element of each asserted claim is found, including for each element that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in each item of prior art that performs the claimed function; and

(4) Any grounds of invalidity based on indefiniteness under 35 U.S.C. § 112(2) or enablement or written description under 35 U.S.C. § 112(1) of any of the asserted claims.

d. Document Production Accompanying Invalidity Contentions: With the "Invalidity Contentions," Defendant shall produce:

(1) Specifications, schematics, artwork, or other documentation sufficient to show the operation of any aspects or elements of an Accused Device identified by Plaintiff in his ¶ 7.a.(3) chart and

(2) A copy of each item of prior art identified pursuant to ¶ 7.c.(1) which does not appear in the file history of the patent(s) at issue. To

the extent any such item is not in English, an English translation of the portion(s) relied upon must be produced.

e. Response to Invalidity contentions. Not later than April 8, 2016, Plaintiff shall serve its "Response to Invalidity Contentions" which must contain the following information:

(1) For each item of asserted prior art, the identification of each limitation of each asserted claim that the party believes is absent from the prior art, except for design patents, where the party shall supply an explanation why the prior art does not anticipate the claim;

(2) If obviousness is alleged, an explanation of why the prior art does not render the asserted claim obvious;

(3) The party's responses shall follow the order of the invalidity chart required under L. Pat. R. 3.3(c), and shall set forth the party's agreement or disagreement with each allegation therein and the written basis thereof; and

(4) The production or the making available for inspection and copying of any document or thing that the party intends to rely on in support of its Responses herein.

f. Non-Infringement Contentions and Responses. Not later than March 11, 2016, Defendant shall serve its "Non- Infringement Contentions and Responses" which must contain the following information:

(1) The written basis for its Non-Infringement Contentions and Responses;

(2) The party's responses shall follow the order of the invalidity chart required under L. Pat. R. 3.1(c), and shall set forth the party's agreement or disagreement with each allegation therein and the written basis thereof; and

(3) The production or the making available for inspection and copying of any document or thing that the party intends to rely on in support of its Responses herein.

g. Amending Contentions.

(1) Leave not required. Each party's contentions shall be deemed to be its final contentions, with the following exception: If a party believes in good faith that the Court's Claim Construction Ruling so requires, not later than 30 days after service by the Court of its Claim Construction Ruling, a party may serve amended contentions without leave of court.

(2) Leave required. Amendment or supplementation of any contentions other than as expressly permitted in ¶ 7.g.(1), may be made only by order of the Court, which shall be entered only upon a showing of good cause.

h. Willfulness: By February 26, 2016, if Defendant will rely on an opinion of counsel as part of a defense to a claim of willful infringement, Defendant shall:

(1) Produce the opinion(s) and any other documents relating to the opinion(s) as to which that party agrees the attorney-client or work product protection has been waived; and

(2) Serve a privilege log identifying any other documents, except those authored by counsel acting solely as trial counsel, relating to the subject matter of the opinion(s) which the party is withholding on the grounds of attorney-client privilege or work product protection.

(3) A party failing to comply with the requirements of this paragraph shall not be permitted to rely on an opinion of counsel as part of a defense to willful infringement absent a stipulation of all parties or by order of the Court, which shall be entered only upon a showing of good cause.

8. Claim Construction Proceedings

a. Exchange of Proposed Terms and Claim Elements for Construction.

(1) Not later February 5, 2016, each party shall simultaneously exchange a list of claim terms, phrases, or clauses which that party contends should be construed by the Court, and identify any claim element which that party contends should be governed by 35 U.S.C. § 112(6).

(2) The parties shall thereafter meet and confer for the purposes of finalizing this list, narrowing or resolving differences, and facilitating the ultimate preparation of a Joint Claim Construction and Pre-hearing Statement.

b. Exchange of Preliminary Claim Constructions and Extrinsic Evidence.

(1) Not later than February 19, 2016, the parties shall simultaneously exchange a preliminary proposed construction of each claim term, phrase, or clause which the parties collectively have identified for claim construction purposes. Each such "Preliminary Claim Construction" shall also, for each element which any party contends is governed by 35 U.S.C. § 112(6), identify the structure(s), act(s), or material(s) corresponding to that element.

(2) At the same time the parties exchange their respective "Preliminary Claim Constructions," they shall each also provide a preliminary identification of extrinsic evidence, including without limitation, dictionary definitions, citations to learned treatises and prior art, and identification of expert witnesses they contend will testify in support of their respective claim constructions. The parties shall identify each such item of extrinsic evidence by production number or produce a copy of any such item not previously produced. With respect to any such witness, percipient or expert, the parties shall

also provide a brief description of the substance of that witness' proposed testimony.

(3) The parties shall thereafter meet and confer for the purposes of narrowing the issues and finalizing preparation of a Joint Claim Construction and Pre-hearing Statement.

c. Joint Claim Construction and Pre-hearing Statement: Not later than March 4, 2016, the parties shall complete and file a Joint Claim Construction and Pre-hearing Statement, which shall contain the following information:

(1) The construction of those claim terms, phrases, or clauses on which the parties agree;

(2) Each party's proposed construction of each disputed claim term, phrase, or clause, together with an identification of all references from the specification or prosecution history that support that construction, and an identification of any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction of the claim or to oppose any other party's proposed construction of the claim, including, but not limited to, as permitted by law, dictionary definitions, citations to learned treatises and prior art, and testimony of percipient and expert witnesses;

(3) The anticipated length of time necessary for the Claim Construction Hearing;

(4) Whether any party proposes to call one or more witnesses, including experts, at the Claim Construction Hearing, the identity of each such witness, and for each expert, a summary of each opinion to be offered in sufficient detail to permit a meaningful deposition of that expert;

(5) A list of any other issues which might appropriately be taken up at a pre-hearing conference prior to the Claim Construction Hearing, and proposed dates, if not previously set, for any such pre-hearing conference; and

(6) a claim construction chart electronically in MS Word format or in such other format as the Court may direct.

d. Completion of Claim Construction Discovery: Witnesses testifying on claim construction issues shall be deposed within 3 weeks of submitting a declaration on claim construction issues.

e. Claim Construction Briefs.

(1) Not later than March 29, 2016, each party shall serve and file an opening brief and any evidence supporting its claim construction.

(2) Not later than May 6, 2016, each party shall serve and file their responsive brief and supporting evidence.

f. Claim Construction Hearing: Subject to the convenience of the Court's calendar, two weeks following submission of the responsive briefing specified in ¶ 8.e.(2), the Court shall conduct a Claim Construction

Hearing, to the extent the parties or the Court believe a hearing is necessary for construction of the claims at issue.

Respectfully submitted,

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Attorneys for Defendant
Wedgewood Village Pharmacy, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on December 14, 2015, the foregoing Jointly Proposed Scheduling Order and Discovery Plan was filed electronically with the Clerk of the Court to be served by operation of the Court's electronic filing system upon counsel of record.

/s/ James J. Kernell

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI

EATON VETERINARY PHARMACEUTICAL, INC. Plaintiff, v. WEDGEWOOD VILLAGE PHARMACY, INC. Defendant,	)	Case Number: 4:15-CV-687-SRB

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF DEFENDANT WEDGEWOOD VILLAGE PHARMACY, INC.

Defendant Wedgewood Village Pharmacy, Inc. ("Wedgewood") hereby files this Answer, Affirmative Defenses, and Counterclaims to the Complaint filed by Eaton Veterinary Pharmaceutical, Inc. ("Eaton" or "Plaintiff") and states:

PARTIES

1. Eaton is a corporation organized and existing under the laws of the State of Delaware, having an address of 711 East Carefree Hwy, Suite 140, Phoenix, Arizona 85085. Eaton possesses all rights, title and interest in U. S. Patent 6,930,127, including the right to sue for infringement.

ANSWER: Wedgewood does not have sufficient knowledge to admit or deny the allegations of this paragraph and on that basis denies them.

2. Defendant Wedgewood Village Pharmacy ("Wedgewood") is a corporation organized and existing under the laws of the State of New Jersey. On information and belief Wedgewood has a principal place of business at 405 Heron Drive, #200, Swedesboro, New Jersey 08085.

ANSWER: Admitted.

JURISDICTION AND VENUE

3. This is a patent infringement action brought under the patent laws of the United States, 35 U.S.C. Section 1 *et seq.* Eaton seeks damages for patent infringement and an

injunction preventing Wedgewood from inducing or contributing to others' use of Eaton's patented technology without its permission.

ANSWER: Wedgewood admits that the complaint purports to bring a claim for induced infringement under 35 U.S.C. § 271(b) for which Eaton asks for both damages and an injunction. Wedgewood specifically denies any infringement, specifically denies that Eaton is entitled to either damages or an injunction, and denies all remaining allegations of this paragraph.

4. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admitted.

5. This Court has personal jurisdiction over Wedgewood because it has purposefully introduced its products into interstate commerce and sold its infringing products in this State and this district.

ANSWER: Denied.

6. Venue in this district is proper under 28 U.S.C. §§ 1391 and 1400 because a substantial part of the events giving rise to the claims asserted herein occurred in this district, and Wedgewood has committed acts of infringement in this district.

ANSWER: Denied.

BACKGROUND

7. This lawsuit stems from the flagrant theft and misuse of valuable intellectual property belonging to Eaton.

ANSWER: Denied.

8. This intellectual property comprises a patented method of treating various ophthalmic diseases in animals. The patent being infringed is U. S. Patent No. 6,930,127 (the "'127 Patent"). Exhibit A.

ANSWER: Denied.

9. The invention comprises the administration of a non-aqueous substance to an animal's affected eye to treat ophthalmic disease, wherein the non-aqueous substance contains a chemical called tacrolimus. The amount of tacrolimus in the substance ranges from 0.00001% to about 10.0% by weight of the substance.

ANSWER: Denied.

10. Wedgewood is a veterinary compounding pharmacy, which prepares pharmaceutical products to meet the needs of a particular animal/patient as prescribed by a doctor of veterinary medicine.

ANSWER: Wedgewood admits that it provides compounding pharmacy services to veterinarians and animal owners to provide medications as prescribed by a doctor of veterinary medicine.

11. On information and belief, Wedgewood employs pharmacists and technicians who have undergone specialized training in veterinary compounding of ophthalmic products.

ANSWER: Wedgewood admits that it employs pharmacists and pharmacy technicians who have necessary training to provide compounding pharmacy services. Wedgewood denies the remaining allegations of this paragraph.

12. On October 16, 2014, a cease and desist letter along with a copy of the '127 Patent was sent to Wedgewood. Exhibit B.

ANSWER: Wedgewood admits that sometime after October 16, 2014 it received a copy of the letter attached to the complaint as Exhibit B with a copy of the '127 patent.

13. Defendant was provided detailed information in the '127 Patent regarding the treatment of chronic eye diseases in dogs.

ANSWER: Denied.

14. Defendant was provided detailed information in the '127 Patent regarding the use of tacrolimus in a non-aqueous lubricant vehicle for treatment of chronic eye diseases in dogs.

ANSWER: Denied.

15. Defendant was provided detailed information in the '127 Patent regarding the method of administering the tacrolimus compound to the eye of an affected animal.

ANSWER: Denied.

16. The primary use of the tacrolimus compound disclosed in the '127 Patent in veterinary medicine is for the treatment of chronic eye diseases in dogs.

ANSWER: Denied.

17. Defendant actively induces its customers to order the tacrolimus compound disclosed in the '127 Patent for the treatment of chronic eye diseases in dogs through advertising on its website, direct sales, publications and catalogs.

ANSWER: Denied.

18. Defendant knew that the tacrolimus compound disclosed in the '127 Patent was adapted for the particular use of treatment of chronic eye diseases in dogs, and that the '127 Patent proscribes that use.

ANSWER: Denied.

19. On May 8, 2015, a second cease and desist letter was sent to Wedgewood. Exhibit C.

ANSWER: Wedgewood admits that sometime after May 8, 2015 it received a copy of the letter attached to the complaint as Exhibit C.

20. On information and belief, when a new prescription for a particular compound is called into Wedgewood, a pharmacist specifically requests information including the disease, the animal to be treated, and the intended use of the compound.

ANSWER: Denied.

21. On information and belief, when Wedgewood fills a prescription for the tacrolimus compound disclosed in the '127 Patent, it knows that the tacrolimus compound will be provided and administered in a manner that infringes one or more claims of the '127 Patent.

ANSWER: Denied.

22. Use of tacrolimus compound for treatment of chronic eye diseases in dogs is a non-standard prescription, which requires the pharmacist to inquire about the health condition of the pet and is filled for a specific pet.

ANSWER: Denied.

23. The chronic eye diseases in dogs disclosed in the '127 patent are chronic conditions that require treatment for the life of the pet.

ANSWER: Denied.

24. On information and belief, Wedgewood is required to inquire from the veterinarian or the customer the health condition of the pet before filling a prescription for the tacrolimus compound disclosed in the '127 Patent.

ANSWER: Denied.

25. On information and belief, Defendant has filled thousands of prescriptions for the tacrolimus compound disclosed in the '127 patent for treatment of chronic eye diseases in dogs.

ANSWER: Denied.

26. In complete disregard for Eaton's intellectual property rights, Defendant willfully infringed Eaton's '127 Patent by using the patented technology or inducing and contributing to others' use of the patented technology, knowing they did not have the right to do so.

ANSWER: Denied.

27. Defendant's actions have infringed and continue to infringe Eaton's '127 Patent.

ANSWER: Denied.

28. On information and belief, on February 21, 2014, Wedgewood was sent a warning letter from the Food and Drug Administration for violations of the Federal Food, Drug, and Cosmetic Act.

ANSWER: Wedgewood admits that it received a warning letter dated February 21, 2014 from the U.S. Food and Drug Administration . This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Wedgewood denies the remaining allegations of this paragraph.

29. Accordingly, at a minimum, Eaton seeks a reasonable royalty, together with such other and further relief is available under 35 U.S.C. § 285.

ANSWER: This paragraph contains a legal conclusion to which no response is required. To the extent a response is required, Wedgewood denies this paragraph.

COUNT I: PATENT INFRINGEMENT

30. Eaton incorporates by reference the foregoing allegations as if fully set forth herein.

ANSWER: Wedgewood incorporates by reference it Answers to the foregoing allegations as if fully set forth herein.

31. Defendant customers directly infringe one or more claims of the '127 Patent by performing all of the steps of one or more claims of the '127 Patent.

ANSWER: Denied.

32. Defendant advertises, sells and offers to sell the tacrolimus compound set forth in the ’127 Patent for the express purpose claimed in the ’127 Patent.

ANSWER: Denied.

33. Defendant actively and knowingly provides the tacrolimus compound set forth in the ’127 Patent to its customers for the express purpose claimed in the ’127 Patent.

ANSWER: Denied.

34. Defendant has committed and is continuing to commit acts of infringement of the ’127 Patent under 35 U.S.C. § 271(b) by inducing its customers to use a method that infringes one or more claims of the ’127 Patent.

ANSWER: Denied.

35. Eaton has been damaged as a direct result of Defendant inducing its customers to use a method that infringes one or more claims of the ’127 Patent.

ANSWER: Denied.

36. Eaton will continue to be damaged unless further infringement is enjoined.

ANSWER: Denied.

37. Eaton is entitled under 35 U.S.C. § 284 to an award of damages adequate to compensate Eaton for Defendant inducing its customers to use a method that infringes one or more claims of the ’127 Patent.

ANSWER: Denied.

38. Eaton is entitled to lost profits or, in the alternative, a reasonable royalty for the infringement and use made of the invention of the ‘127 Patent by Defendant and its customers, all together with interest and costs.

ANSWER: Denied.

COUNT II: WILLFUL INFRINGEMENT

39. Eaton incorporates by reference his foregoing allegations as if fully set forth herein.

ANSWER: Wedgewood incorporates by reference it Answers to the foregoing allegations as if fully set forth herein.

40. Wedgewood had actual notice of the ’127 Patent and Eaton’s infringement allegations.

ANSWER: Denied.

41. Wedgewood's past and continuing infringement of the '127 Patent has been deliberate and willful.

ANSWER: Denied.

42. Wedgewood's conduct warrants an award of treble damages pursuant to 35 U.S.C. § 284. Moreover, this is an exceptional case as set forth in 35 U.S.C. § 285 warranting an award of attorneys' fees.

ANSWER: Denied.

DEMAND FOR JURY TRIAL

Wedgewood demands a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Wedgewood respectfully requests that this Honorable Court deny Eaton any of the relief it requests.

AFFIRMATIVE DEFENSES

Without prejudice to the Answers and denials set forth in its responses to paragraphs 1-42 above, Wedgewood sets forth the following affirmative defenses. In stating these defenses, Wedgewood does not assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiff bears the burden of proof.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiffs have failed to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE
(Non-Infringement)

Wedgewood does not induce infringement of any valid, enforceable claim of the '127 patent, and no third party directly infringes any valid, enforceable claim of the '127 patent.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

One or more claims of the '127 patent is invalid for failure to comply with one or more of the conditions set forth in 35 U.S.C. §§ 101 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and the defenses recognized in 35 U.S.C. § 282(b).

FOURTH AFFIRMATIVE DEFENSE
(Failure to State an Exceptional Case)

The Complaint fails to state a claim for an exceptional case pursuant to 35 U.S.C. § 285.

FIFTH AFFIRMATIVE DEFENSE
(No willful infringement)

Wedgewood has not willfully infringed any valid, enforceable claim of the '127 patent.

SIXTH AFFIRMATIVE DEFENSE
(Equitable Estoppel)

Equitable estoppel bars Eaton from asserting the '127 patent against Wedgewood.

SEVENTH AFFIRMATIVE DEFENSE
(Laches)

Eaton is barred by the doctrine of Laches from collecting any damages prior to filing of the complaint.

EIGHTH AFFIRMATIVE DEFENSE
(Patent Misuse)

Eaton's assertion of the '127 patent against Wedgewood is barred by the doctrine of patent misuse.

NINTH AFFIRMATIVE DEFENSE
(Unclean Hands)

Eaton's assertion of the '127 patent against Wedgewood is barred by the doctrine of unclean hands.

TENTH AFFIRMATIVE DEFENSE
(Additional Defenses)

Wedgewood reserves the right to present any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS AND CROSSCLAIMS

Defendant/Counterclaimant Wedgewood Village Pharmacy, Inc. ("Wedgewood") bring the following Counterclaims against Plaintiff/Counterdefendant Eaton Veterinary Pharmaceuticals, Inc. ("Eaton").

1. This is a counterclaim and Third-Party Claim based upon an actual controversy between the parties concerning the invalidity and/or noninfringement of U.S. Patent No. 6,930,127 ("the '127 patent").

Parties

2. Wedgewood Village Pharmacy ("Wedgewood") is a corporation organized and existing under the laws of the State of New Jersey. Wedgewood has a principal place of business at 405 Heron Drive, #200, Swedesboro, New Jersey 08085.

3. On information and belief, Eaton Veterinary Pharmaceuticals, Inc. ("Eaton") is a corporation organized and existing under the laws of the State of Delaware, having an address of 711 East Carefree Hwy, Suite 140, Phoenix, Arizona 85085.

4. On information and belief, Eaton is not a licensed pharmacy.

5. On information and belief, Eaton has not submitted any application to FDA for marketing approval of any drug product or drug substance.

6. On information and belief, Eaton has not submitted any application to FDA for marketing approval of any tacrolimus drug product or tacrolimus drug substance.

7. On information and belief, Eaton does not make or sell any drug products, either FDA-approved drug products.

8. On information and belief, Eaton does not make or sell any medications compounded as part of the licensed practice of pharmacy.

Jurisdiction and Venue

9. Wedgewood seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

10. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has jurisdiction over Eaton based at least on the filing of this lawsuit by Eaton in this jurisdiction.

12. Although venue is more appropriate in New Jersey, venue is proper under 28 U.S.C. §§ 1391 and 1400, and by Eaton's choice of forum.

Background

13. Researchers at Fujisawa Pharmaceuticals discovered tacrolimus in the mid-1980s.

14. FDA first approved a tacrolimus product for use in humans in 1994.

15. There is no FDA-approved commercially available tacrolimus product for veterinary use. Accordingly, veterinary compounding pharmacies, such as Wedgewood, are the only source of ophthalmic veterinary tacrolimus medications.

16. Veterinarians can prescribe ophthalmic veterinary tacrolimus medications for treatment of a wide variety of diseases or disorders other than the specific disease, Pannus, to which the claims of the '127 patent are directed.

17. The treating veterinarian makes the treatment decision regarding what medication or treatment regimen is appropriate for the animal patients under his or her care.

18. The patent application that eventually led to the '127 patent was filed on June 18, 2003, listing Kris R. Stiles as the inventor and identifying Eaton Veterinary Laboratories, Inc. as the assignee.

19. Among the original claims filed with the patent application that led to the '127 patent was a claim reciting:

> 1. A method of treating an ophthalmic disorder of an animal, comprising:
>
> a) providing a quantity of a composition consisting essentially of a mixture of an effective amount of tacrolimus and a non-aqueous lubricating vehicle; and
>
> b) administering a quantity of said composition to the eye of said animal.

20. The Patent Office rejected the original claims, including the claim recited above, for failure to comply with the written description requirement of 35 U.S.C. § 112 and for being anticipated by two separate prior art references under 35 U.S.C. § 102.

21. In response to the rejection from the Patent Office, the patent applicant narrowed the claims by amendment. Claim 1 was amended to recite:

> A method of treating an ophthalmic disease of a quadruped animal, said disease selected form the group consisting essentially of conjunctival disorders of the third eyelid, allergic conjunctivitis, blepharoconjunctivitis, follicular conjunctivitis, viral conjunctivitis, uveitis, chronic superficial keratitis, chronic keratoconjunctivitis sicca, feline eosinophilic keratoconjunctivitis, Uberreiter's syndrome, Pannus, ocular rosacea and phacoanaphylactic endophthalmitis, said method comprising the steps of:
>
> a) providing a quantity of a composition consisting essentially of a mixture of an effective amount of tacrolimus and a non-aqueous lubricating vehicle; and
>
> b) administering a quantity of said composition to the eye of said animal.

22. On August 11, 2005, the Patent Office rejected the amended claims, including amended claim 1, as obvious under 35 U.S.C. § 103.

23. In response to the August 11, 2005 obviousness rejection, the patent applicant cancelled amended claim 1.

24. In response to the August 11, 2005 obviousness rejection, the patent applicant amended the claims leaving a single independent claim reciting:

> A method of treating pannus in canines having said disease and comprising the steps of:
>
> a) providing a quantity of a composition consisting essentially of an effective amount of tacrolimus in a pharmaceutically acceptable non-aqueous lubricant vehicle; and
>
> administering a quantity of said composition to the third eyelid of an affected canine.

25. After the patent applicant narrowed the claims, the Patent Office issued a notice of allowance, with the above recited claim from paragraph 24 as the sole independent claim.

26. The '127 patent issued on or about August 16, 2005, including the above recited claim from paragraph 24 as the sole independent claim.

27. The '127 patent does not give Eaton the right to exclude others from making, using, selling, or offering to sell tacrolimus compositions in a non-aqueous vehicle.

28. The '127 patent does not give Eaton the right to exclude others from making, using, selling, or offering to sell tacrolimus compositions in a non-aqueous vehicle for treatment of diseases or disorders other than pannus.

29. The '127 patent does not give Eaton the right to exclude others from making, using, selling, or offering to sell tacrolimus compositions in a non-aqueous vehicle for administration in ways other than administration to the third eyelid of an affected canine.

30. On or about October 16, 2014, over nine years after the patent issued, Eaton sent to Wedgewood a letter demanding that Wedgewood cease and desist compounding tacrolimus in a non-aqueous vehicle. (*See* D.E. 1, Ex. B.)

31. Eaton's October 16, 2014 letter demanded an upfront license fee and a continuing royalty on all sales of any tacrolimus composition in a non-aqueous vehicle regardless of whether the composition was used in a manner that practiced the claimed method of the '127 patent, including for treatment of diseases or disorders other than pannus in canines and administration to sites other than the third eyelid of an affected canine. (*See* D.E. 1, Ex. B.)

32. Eaton's October 16, 2014 letter does not assert that Wedgewood induces infringement of the '127 patent.

33. On or about May 8, 2015, Eaton sent to Wedgewood a second letter demanding that Wedgewood cease and desist compounding tacrolimus in a non-aqueous vehicle. (*See* D.E. 1, Ex. C.)

34. Eaton's May 8, 2015 letter again demanded an upfront license fee and a continuing royalty on all sales of any tacrolimus composition in a non-aqueous vehicle regardless of whether the composition used in a manner that practiced the claimed method of the '127 patent, including administration to sites other than the third eyelid of an affected canine, and for treatment of diseases or disorders other than pannus in canines. (*See* D.E. 1, Ex. C.)

35. Eaton's May 8, 2015 letter does not assert that Wedgewood induces infringement of the '127 patent.

36. Eaton has filed in this Court an infringement action alleging that Wedgewood induces infringement of the '127 patent under 35 U.S.C. § 271(b).

37. Wedgewood has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of, any valid and enforceable claim of the '127 patent.

38. Wedgewood has further asserted that the claims of the '127 patent are invalid for failure to satisfy one or more provisions of the United States Patent laws, including 35 U.S.C. §§ 101, 102, 103, 112, and the defenses recognized in 35 U.S.C. § 282(b).

39. This case is an exceptional one, and Wedgewood is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

40. In view of the foregoing, a conflict of asserted rights has arisen between Wedgewood and Eaton with respect to the noninfringement and invalidity of the relevant claims of the '127 patent, and to Wedgewood's right to provide compounding pharmacy services with respect to tacrolimus that are not claimed in the '127 patent. An actual controversy therefore exists between Wedgewood and Eaton.

FIRST COUNTERCLAIM
DECLARATION OF NONINFRINGEMENT OF THE '127 PATENT

41. Wedgewood realleges Paragraphs 1-40 as though fully set forth herein.

42. Wedgewood does not induce infringement of any valid, enforceable claim of the '127 patent.

43. Wedgewood is entitled to a judicial determination that the sale, offer for sale, preparation, or use of its compounded tacrolimus medications does not infringe or induce infringement of any valid and enforceable claim of the '127 patent.

SECOND COUNTERCLAIM
DECLARATION OF INVALIDITY OF THE '127 PATENT

44. Wedgewood realleges Paragraphs 1-43 as though fully set forth herein.

45. The claims of the ’127 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 101 *et seq*., including, but not limited to, the requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

46. Wedgewood is entitled to a judicial determination that the claims of the ’127 patent are invalid.

THIRD COUNTERCLAIM
PATENT MISUSE

47. Wedgewood realleges Paragraphs 1-46 as though fully set forth herein.

48. Eaton is exceeding the scope of the ’127 patent to exclude Wedgewood and to extract payment form Wedgewood for producing and selling compositions which do not employ or follow the claimed subject matter of the ‘127 patent

49. Eaton’s demands that Wedgewood cease and desist compounding tacrolimus in a non-aqueous vehicle or pay a license and continuing royalty to sales of compounded tacrolimus in a non-aqueous vehicle constitute patent misuse of the ‘127 patent.

50. Eaton is thereby precluded from asserting the ‘127 patent against Wedgewood.

DEMAND FOR JUDGMENT

WHEREFORE, Wedgewood prays for the following relief:

A. That all claims against Wedgewood be dismissed with prejudice and that all relief requested by Eaton be denied;

B. That a judgment be entered declaring that Wedgewood has not and does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid, enforceable claim of U.S. Patent No. 6,930,127; and further that Wedgewood has a lawful right to make,

use, sell, and/or offer to sell its compounded tacrolimus medications in the United States;

C. That a judgment be entered declaring the claims of U.S. Patent Nos. 6,930,127 invalid;

D. That Eaton and its agents, representatives, attorneys, and those persons in active concert or participation with it who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Wedgewood or any of its customers, dealers or suppliers, or any prospective or present sellers, dealers, or distributors, or charging any of them either orally or in writing with infringement of U.S. Patent Nos. 6,930,127;

E. That a judgment be entered, declaring this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Wedgewood is therefore entitled to recover its reasonable attorneys' fees upon prevailing in this action;

F. That Wedgewood be awarded costs, attorneys' fees and other relief, both legal and equitable, to which it may be justly entitled; and

That Wedgewood be awarded such other ant further relief as is just and proper.

DATED: December 17, 2015 WEDGEWOOD VILLAGE PHARMACY, INC.

BY: /s/ Robert M. Thompson

Robert Thompson, Mo. Bar #38156
Curtis Shank, Mo. Bar #66221
BRYAN CAVE LLP
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pcgallagher@duanemorris.com

Attorneys for Defendant Wedgewood Village Pharmacy, Inc.

CERTIFICATE OF SERVICE

I, Robert Thompson, hereby certify that on December 17, 2015, I caused a true and correct copy of the Answer to Complaint to be served upon the following individuals via CM/ECF:

James J. Kernell
Kyle D. Donnelly
Erickson, Kernell, Derusseau & Gleypas, LLC
8900 State Line Road, Suite 500
Leawood, Kansas 66206
Attorneys for Plaintiff
Eaton Veterinary Pharmaceutical, Inc.

/s/ Robert M. Thompson

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

EATON VETERINARY PHARMACEUTICAL, INC.,	)	
Plaintiff,	)	
v.	)	Case No. 4:15-cv-00687-SRB
WEDGEWOOD VILLAGE PHARMACY, INC.,	)	
Defendant.	)	

CONSENT MOTION FOR DISCOVERY CONFIDENTIALITY ORDER

The parties have agreed to a Discovery Confidentiality Order to apply to discovery documents, information and testimony produced or disclosed in the above-identified case and respectfully move this Court for an order entering the Discovery Confidentiality Order attached as Exhibit A and submitted to this Court via email to tracy_diefenbach@mow.uscourts.gov.

January 7, 2016

Respectfully submitted,

By: */s/ James J. Kernell*

James J. Kernell, #48850
Kyle D. Donnelly, #KS-000879
ERICKSON KERNELL DERUSSEAU & KLEYPAS, LLC
8900 State Line Road, Suite 500
Leawood, Kansas 66206
Telephone: (913) 549-4700
Facsimile: (913) 549-4646

Attorneys for Plaintiff
Eaton Veterinary Pharmaceutical, Inc.

CERTIFICATE OF SERVICE

I certify that on the 7th day of January 2016, the foregoing was filed with the Clerk of the Court to be served via the Court's ECF system upon counsel of record.

/s/ James J. Kernell

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

EATON VETERINARY PHARMACEUTICAL, INC.,	)	
Plaintiff,	)	
v.	)	Case No. 4:15-cv-00687-SRB
WEDGEWOOD VILLAGE PHARMACY, INC.,	)	
Defendant.	)	

PLAINTIFF'S MOTION TO DISMISS AND STRIKE DEFENDANT'S COUNTERCLAIMS AND AFFIRMATIVE DEFENSES

Comes now Plaintiff Eaton Veterinary Pharmaceutical, Inc. ("Plaintiff" or "Eaton") and pursuant to Fed. R. Civ. P. 8(b), 8(c), 12(b)(6) and 12(f), moves the Court to dismiss Defendant Wedgewood Village Pharmacy, Inc.'s counterclaims and second, third, fourth, fifth, sixth, seventh, eighth and ninth affirmative defenses.

The first counterclaim is duplicative of Eaton's affirmative claim in this case, which courts routinely dismiss such "mirror-image" counterclaims.

Wedgewood's second, fourth and fifth affirmative defenses are merely rebuttals to plaintiff's claims and should be stricken.

Wedgewood's tenth affirmative defensive reserving additional affirmative defenses is not an affirmative defense and must be stricken.

Respectfully submitted,

By: */s/ James J. Kernell*
James J. Kernell, #48850
Kyle D. Donnelly, #KS-000879
ERICKSON KERNELL DERUSSEAU
& KLEYPAS, LLC
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Telephone: (913) 549-4700
Facsimile: (913) 549-4646

Attorneys for Plaintiff
Eaton Veterinary Pharmaceutical, Inc.

CERTIFICATE OF SERVICE

I certify that on the 7th day of January 2016, the foregoing was served via the Court's ECF system upon counsel of record.

/s/ James J. Kernell

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI

EATON VETERINARY PHARMACEUTICAL, INC. Plaintiff, v. WEDGEWOOD VILLAGE PHARMACY, INC. Defendant,	)	Case Number: 4:15-CV-687-SRB

DISCOVERY CONFIDENTIALITY ORDER

It appearing that discovery in the above-captioned action is likely to involve the disclosure of confidential information, it is ORDERED as follows:

1. Any party to this litigation and any third-party shall have the right to designate as "Confidential" and subject to this Order any information, document, or thing, or portion of any document or thing: (a) that contains trade secrets, competitively sensitive technical, marketing, financial, sales or other confidential business information, or (b) that contains private or confidential personal information, or (c) that contains information received in confidence from third parties, or (d) which the producing party otherwise believes in good faith to be entitled to protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure. Any party to this litigation or any third party covered by this Order, who produces or discloses any Confidential material, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: "CONFIDENTIAL" or "CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER" (hereinafter "Confidential").

2. Any party to this litigation and any third-party shall have the right to designate as "Attorneys' Eyes Only" and subject to this Order any information, document, or thing, or portion of any document or thing that contains highly sensitive business or personal information, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of the designating party. Any party to this litigation or any third party who is covered by this Order, who produces or discloses any Attorneys' Eyes Only material, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: "ATTORNEYS' EYES ONLY" or "ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER" (hereinafter "Attorneys' Eyes Only").

3. All Confidential material shall be used by the receiving party solely for purposes of the prosecution or defense of this action, shall not be used by the receiving party for any business, commercial, competitive, personal or other purpose, and shall not be disclosed by the receiving party to anyone other than those set forth in Paragraph 4, unless and until the restrictions herein are removed either by written agreement of counsel for the parties, or by Order of the Court. It is, however, understood that counsel for a party may give advice and opinions to his or her client solely relating to the above-captioned action based on his or her evaluation of Confidential material, provided that such advice and opinions shall not reveal the content of such Confidential material except by prior written agreement of counsel for the parties, or by Order of the Court.

4. Confidential material and the contents of Confidential material may be disclosed only to the following individuals under the following conditions:

a. Outside counsel (herein defined as any attorney at the parties' outside law firms) and relevant in-house counsel for the parties;

b. Outside experts or consultants retained by outside counsel for purposes of this action, provided they have signed a non-disclosure agreement in the form attached hereto as Appendix 1;

c. Secretarial, paralegal, clerical, duplicating and data processing personnel of the foregoing;

d. The Court and court personnel;

e. Any deponent may be shown or examined on any information, document or thing designated Confidential if it appears that the witness authored or received a copy of it, the witness was involved in the subject matter described therein, the witness is or was employed by the party who produced the information, document or thing, or if the producing party consents to such disclosure;

f. Vendors retained by or for the parties to assist in preparing for pretrial discovery, trial and/or hearings including, but not limited to, court reporters, litigation support personnel, jury consultants, individuals to prepare demonstrative and audiovisual aids for use in the courtroom or in depositions or mock jury sessions, as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials; and

g. Two designated representatives for each party responsible for overseeing this litigation, each of whom does not have responsibility or involvement related to patent prosecution or patent procurement, and each of whom must execute the Confidentiality Agreement attached as Appendix 1. In the event that one of the

representatives designated under this paragraph ceases to have responsibilities relating to this litigation, a party may designate another representative to replace such person upon giving written notice of such change to all parties; however, the new individual must also execute the Confidentiality Agreement attached as Appendix 1.

5. Confidential material shall be used only by individuals permitted access to it under Paragraph 4. Confidential material, copies thereof, and the information contained therein, shall not be disclosed in any manner to any other individual, until and unless (a) outside counsel for the party asserting confidentiality waives the claim of confidentiality, or (b) the Court orders such disclosure.

6. With respect to any depositions that involve a disclosure of Confidential material of a party to this action, such party shall have until thirty (30) days after receipt of the deposition transcript within which to inform all other parties that portions of the transcript are to be designated Confidential, which period may be extended by agreement of the parties. No such deposition transcript shall be disclosed to any individual other than the individuals described in Paragraph 4(a), (b), (c), (d) and (f) above and the deponent during these thirty (30) days, and no individual attending such a deposition shall disclose the contents of the deposition to any individual other than those described in Paragraph 4(a), (b), (c), (d) and (f) above during said thirty (30) days. Upon being informed that certain portions of a deposition are to be designated as Confidential, all parties shall immediately cause each copy of the transcript in its custody or control to be appropriately marked and limit disclosure of that transcript in accordance with Paragraphs 3 and 4.

7. Material produced and marked as Attorneys' Eyes Only may be disclosed only individuals described in Paragraph 4(a)-(f).

8. If counsel for a party receiving documents or information designated as Confidential or Attorneys' Eyes Only hereunder objects to such designation of any or all of such items, the following procedure shall apply:

a. Counsel for the objecting party shall serve on the designating party or third party a written objection to such designation, which shall describe with particularity the documents or information in question and shall state the grounds for objection. Counsel for the designating party or third party shall respond in writing to such objection within 14 days, and shall state with particularity the grounds for asserting that the document or information is Confidential or Attorneys' Eyes Only. If no timely written response is made to the objection, the challenged designation will be deemed to be void. If the designating party or nonparty makes a timely response to such objection asserting the propriety of the designation, counsel shall then confer in good faith in an effort to resolve the dispute.

b. If a dispute as to a Confidential or Attorneys' Eyes Only designation of a document or item of information cannot be resolved by agreement, the proponent of the designation being challenged shall present the dispute to the Court initially by telephone or letter, in accordance with Local Civil Rule 37.1(a)(1), before filing a formal motion for an order regarding the challenged designation. The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute.

9. Material designated by a party as Confidential or Attorneys' Eyes Only that another party wishes to file with the Court must be filed under seal in accordance with the Federal Rules of Civil Procedure and Local Civil Rules.

10. To the extent consistent with applicable law, the inadvertent or unintentional disclosure of Confidential or Attorneys Eyes Only material that should have been designated as such, regardless of whether the information, document or thing was so designated at the time of disclosure, shall not be deemed a waiver in whole or in part of a party's claim of confidentiality, either as to the specific information, document or thing disclosed or as to any other material or information concerning the same or related subject matter. Such inadvertent or unintentional disclosure may be rectified by notifying in writing counsel for all parties to whom the material was disclosed that the material should have been designated Confidential or Attorneys Eyes Only within a reasonable time after disclosure. Such notice shall constitute a designation of the information, document or thing as Confidential or Attorneys Eyes Only under this Discovery Confidentiality Order.

11. When the inadvertent or mistaken disclosure of any information, document or thing protected by privilege or work-product immunity is discovered by the producing party and brought to the attention of the receiving party, the receiving party's treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5)(B). Such inadvertent or mistaken disclosure of such information, document or thing shall not by itself constitute a waiver by the producing party of any claims of privilege or work-product immunity. However, nothing herein restricts the right of the receiving party to challenge the producing party's claim of privilege if appropriate within a reasonable time after receiving notice of the inadvertent or mistaken disclosure.

12. No information that is in the public domain or which is already known by the receiving party through proper means or which is or becomes available to a party from a source other than the party asserting confidentiality, rightfully in possession of such information on a non-confidential basis, shall be deemed or considered to be Confidential material under this Discovery Confidentiality Order.

13. This Discovery Confidentiality Order shall not deprive any party of its right to object to discovery by any other party or on any otherwise permitted ground. This Discovery Confidentiality Order is being entered without prejudice to the right of any party to move the Court for modification or for relief from any of its terms.

14. This Discovery Confidentiality Order shall survive the termination of this action and shall remain in full force and effect unless modified by an Order of this Court or by the written stipulation of the parties filed with the Court.

15. Upon final conclusion of this litigation, each party or other individual subject to the terms hereof shall be under an obligation to assemble and to return to the originating source all originals and unmarked copies of documents and things containing Confidential or Attorneys Eyes Only material and to destroy, should such source so request, all copies of Confidential material that contain and/or constitute attorney work product as well as excerpts, summaries and digests revealing Confidential material; provided, however, that counsel may retain complete copies of all transcripts and pleadings including any exhibits attached thereto for archival purposes, subject to the provisions of this Discovery Confidentiality Order.

IT IS SO ORDERED.

DATED: January 8, 2016

Stephen R. Bough, United States District Judge

Appendix 1

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI

EATON VETERINARY PHARMACEUTICAL, INC.	)	
Plaintiff,	)	
v.	)	Case Number: 4:15-CV-687-SRB
WEDGEWOOD VILLAGE PHARMACY, INC.	)	
Defendant,	)	

DECLARATION AND CONFIDENTIALITY UNDERTAKING

I certify that I have received and carefully read the Discovery Confidentiality Order in this action and that I fully understand the terms of the Order. I recognize that I am bound by the terms of that Order, and I agree to comply with those terms. I hereby consent to the personal jurisdiction of the United States District Court, Western District of Missouri, for any proceedings involving the enforcement of that Order. I declare under penalty of perjury under the laws of the United States of America that this Declaration and Confidentiality Undertaking is true and correct.

EXECUTED this _____day of _____, _____.

_____
Name

_____
Signature

_____
Present Employer or Other Business Affiliation

_____
Business Address

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

EATON VETERINARY PHARMACEUTICAL, INC. *A Delaware Corporation,*	)	
Plaintiff,	)	
v.	)	Case No. 4:15-cv-00687-SRB
WEDGEWOOD VILLAGE PHARMACY, *a New Jersey Corporation,*	)	
Defendant.	)	

SCHEDULING AND TRIAL ORDER FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 16(b) and 26(f), and upon consideration of the parties' proposals in the matter, the following schedule is hereby established:

1. TRIAL SETTING. This case is scheduled for a jury trial, commencing at **9:00 a.m., on May 22, 2017**, in Courtroom 7B at the United States District Courthouse in Kansas City, Missouri.
2. PRETRIAL CONFERENCE. A final pretrial conference in this case will be held at **April 28, 2017 at 10:00 a.m.** in Courtroom 7B, at the United States District Courthouse in Kansas City**,** Missouri**.** Lead trial counsel shall participate in this conference.
3. MOTION TO AMEND PLEADINGS. Any motion to amend the pleadings shall be filed on or before **January 15, 2016**.
4. MOTION TO JOIN ADDITIONAL PARTIES. Any motion to join additional parties shall be filed on or before **January 15, 2016**.
5. DISCOVERY
    a. DISCOVERY DEADLINE.

All pretrial discovery authorized by the Federal Rules of Civil Procedure shall be completed on or before **November 1, 2016** ("Closure Date"). This means that all discovery shall be completed, not simply submitted, on the Closure Date. Accordingly, all discovery requests and depositions shall be submitted and/or scheduled prior to the Closure Date and allow sufficient time for completion within the time specified by the Federal Rules of Civil Procedure, the Local Court Rules, and/or orders of this Court. Discovery shall not be conducted after the Closure Date, except by Order of the Court for good cause shown. Nothing contained herein shall excuse a party from the continuing obligation to update discovery responses in accordance with Fed. R. Civ. P. 26(e).

b. DISCOVERY MOTIONS.

The Court will not entertain any discovery motion absent full compliance with Local Rule 37.1. In the event that a teleconference is needed, email your request to the Courtroom Deputy at tracy_diefenbach@mow.uscourts.gov. A memorandum of the discovery dispute, not to exceed two pages in length, should be electronically submitted by each party no later than twenty-four hours prior to the teleconference.

c. EXPERT DESIGNATION DEADLINES.

Each plaintiff shall designate any expert witnesses it intends to call at trial on or before **August 4, 2016**. Each defendant shall designate any expert witnesses it intends to call at trial on or before **September 15, 2016**. This paragraph applies to all witnesses from whom expert opinions will be elicited at trial, regardless of whether the witness was specially retained to provide trial testimony. Each party shall ensure compliance with Fed. R. Civ. P. 26(a)(2)(B) at the time of the party's expert witness designations. Expert witnesses may testify only as to matters contained in the report required by Rule 26(a)(2)(B), unless leave of Court is granted upon good cause shown.

With respect to treating physicians, coroners and like professionals not retained to testify for a party, the report requirements of this Order may be satisfied by providing a copy of all the treating physician's files, records and notes relating to the treating physician's patient to the opposing party. For the purpose of this paragraph, a "treating physician" is a doctor (including psychiatrist, dentist or other practitioner of the healing arts) retained by a party prior to retaining counsel in this matter. A treating physician will not be allowed to give expert testimony beyond the treatment provided by said physician unless designated as an expert. A treating physician who will provide expert testimony beyond the treatment provided by said physician must further comply with the requirements of this Order.

6. DISPOSITIVE MOTION DEADLINE. All dispositive motions, except those under Rule 12(h)(2) or (3), shall be filed on or before **December 16, 2016**. All dispositive motions shall have a separate section wherein each statement of fact is individually numbered so that any party opposing such motion may refer specifically to a genuine issue of material fact. Suggestions in opposition to a dispositive motion shall begin with a concise listing of material facts as to which the party contends a genuine dispute exists. All motions for summary judgment shall comply with Local Rules 7.0 and 56.1.

7. *DAUBERT* MOTION DEADLINE: All motions to strike expert designations or preclude expert testimony premised on *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), shall be filed on or before **December 16, 2016**. The deadline for filing motions in limine does not apply to these motions. Failure to file a *Daubert* motion prior to this deadline will constitute waiver of any arguments based on *Daubert*.

8. PRETRIAL CONFERENCE DOCUMENT DEADLINES. The documents listed below shall be filed prior to the pretrial conference.

    a. Motions in Limine. Motions in limine shall be filed at least ten (10) business days prior to the final pretrial conference. Responses to motions in limine shall be filed at least three (3) business days prior to the final pretrial conference. In order to ensure efficient use of trial time, the parties are encouraged to file motions in limine relating to key evidentiary issues.

    b. Stipulation of Uncontroverted Facts. At least three (3) business days prior to the final pretrial conference, the parties may file a stipulation of any uncontroverted facts.

    c. Witness List. At least ten (10) business days prior to the final pretrial conference, each party shall file and serve a list of all witnesses who may be called to testify at trial. If a witness is not listed by a party, that witness will not be permitted to testify absent leave of Court and then only for the purpose of unanticipated rebuttal or impeachment.

    d. Exhibit Index. At least five (5) business days prior to the final pretrial conference, each party shall file and serve an exhibit index of all exhibits that may

be offered at trial. If an exhibit is not listed by a party, that exhibit will not be admitted absent leave of Court. The exhibit index should be prepared on a form provided by the Clerk's office that can be found at http://www.mow.uscourts.gov/forms.html#district. Each exhibit will be designated as either "Plaintiff's" or "Defendant's," numbered with an Arabic numeral, and described following the enumeration. If an exhibit consists of more than one (1) page or part, the number of pages or parts shall be included in the description. The exhibit number must be marked on each exhibit at the time of listing. It is not necessary to include exhibits to be used only for impeachment or rebuttal purposes. After the time for filing the exhibit index has expired, no supplemental or amended index will be filed without leave of Court for good cause shown.

e. Stipulation as to the Admissibility of Evidence. At least three (3) business days prior to the final pretrial conference, the parties shall file a stipulation as to the admissibility of evidence, listing the exhibits for which authenticity and foundation are not contested.

f. Designation of Deposition Testimony. Fifteen (15) business days prior to the final pretrial conference, each party shall file and serve a designation, by page and line number, of any deposition testimony to be offered in evidence by that party.

g. Objections to Designated Deposition Testimony and Counter Designation. At least ten (10) business days prior to the final pretrial conference, each party shall file and serve:

    i. Any objections to proposed deposition testimony designated by any other party; and

    ii. A designation, by page and line number, of any deposition testimony to be offered as counter-designation to deposition testimony designated by other parties.

h. Objections to Counter Designations. At least seven (7) business days prior to the final pretrial conference, each party shall file and serve any objections to proposed deposition testimony offered as a counter-designation by other parties.

i. Submission of Deposition Designations. At least seven (7) business days prior to the final pretrial conference, the Court should receive deposition designations in the following manner:

    i. The parties are to jointly submit one mini-script copy of each designated deposition.

    ii. Each party is to highlight the portion of the deposition they want to designate, including counter-designations.

iii. Each party should use a different highlight color to indicate their designations (for example, plaintiff uses yellow; defendant uses blue).

iv. Each party should also indicate their objections on the actual deposition by bracketing those portions in the margin of the deposition, again using a different color to indicate the portion to which each party objects.

v. Each party should submit to the Court a Word version document of the Objections to Deposition Designations that the party filed in CM/ECF. Send that via email to the Courtroom Deputy at tracy_diefenbach@mow.uscourts.gov.

j. Jury Instructions.

i. At least ten (10) business days prior to the final pretrial conference, the parties shall jointly file an original (without sources) set and an annotated (with sources) set of proposed jury instructions. Proposed instructions shall reflect the authorities upon which the instruction is based and should be taken from or drawn in the manner of *Model Civil Jury Instructions for the District of Courts of the Eighth Circuit* and/or *Missouri Approved Instructions* (MAI) where available and appropriate. All instructions shall be designated as Instruction No. ___.

ii. The Court prefers to receive joint instructions from the parties. Separate instructions are appropriate only when the parties cannot agree upon a specific instruction. In that instance, the parties shall jointly submit the instructions upon which they agree. Each party shall submit its proposed version of the instructions upon which the parties do not agree, along with a written objection to the other party's version.

iii. The instructions should also be submitted to the Court electronically, in Word format. Instructions should be sent via email to the Courtroom Deputy at tracy_diefenbach@mow.uscourts.gov.

9. TRIAL DOCUMENT DEADLINES AND TRIAL PROCEDURE.

a. Trial Brief. At least five (5) business days prior to trial, counsel for each party may file a trial brief stating the party's factual and legal contentions in the case. The trial brief should address any important evidentiary issues.

b. Jury Statement. At least five (5) business days prior to trial, counsel for each party shall agree upon a statement to be read to the jury setting forth the background of the case and the claims to be asserted. This statement will be read to the jury panel prior to voir dire. The jury statement shall be emailed in Word format to the Courtroom Deputy at tracy_diefenbach@mow.uscourts.gov.

c. The Court may place time limits on opening statements, and direct and cross-examination of all witnesses. Counsel should be prepared to support their representations as to the length of trial.

10. MISCELLANEOUS.

a. All motions for extension of time pursuant to Fed. R. Civ. P. 6(b), 31, 33, 34, or 36 should be filed at least seven (7) days before the date of the original deadline and must state:

i. The date when the pleading, response, or other action is/was first due;

ii. The number of previous extensions and the date the last extension expires;

iii. The cause for the requested extension, including a statement as to why the action due has not been completed in the allotted time; and

iv. Whether the requested extension is approved or opposed by opposing counsel (agreement by counsel of a requested extension is not binding on the Court).

b. All motions requesting leave to depart from Local Rule 7.0(f) page limitation must state:

i. The number of previous requests for leave;

ii. The particular reason for the request for leave, including a specific statement as to why the action due cannot be completed within the allotted page limit; and

iii. Whether the request for leave is approved or opposed by opposing counsel (agreement by counsel of a request for leave is not binding on the Court).

c. The parties should not submit proposed orders in conjunction with routine motions, *e.g.* motions for extension of time and motions to modify the scheduling order. The parties shall submit proposed orders in conjunction with all motions, other than dispositive motions, in which a specific, substantive ruling is sought by the Court, *e.g.* motions for entry of consent judgment, motions for temporary restraining order, motions for entry of a preliminary injunction, and motions for entry of a protective order. Such proposed orders shall be emailed in Word format to the Courtroom Deputy at tracy_diefenbach@mow.uscourts.gov.

d. The dispositive motion date, final pretrial conference date, and trial date shall be changed only by leave of Court.

e. Any questions about this scheduling order or the procedures to be followed when practicing in this division should be directed to the Courtroom Deputy, Tracy Diefenbach, at tracy_diefenbach@mow.uscourts.gov.

IT IS SO ORDERED.

/s/ Stephen R. Bough
STEPHEN R. BOUGH
UNITED STATES DISTRICT JUDGE

Dated: January 8, 2016

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on the 3rd day of February 2016, the Response Brief of Eaton Veterinary Pharmaceutical, Inc. with Appendix was electronically filed with the Clerk of the Court.

Two copies of this Response Brief with Appendix to be served upon each of the following parties via Federal Express delivery:

Rachel Pontikes
Kevin Nelson
Patrick Gallagher
DUANE MORRIS LLP
190 South LaSalle Street
Chicago, Illinois 60603

The Honorable Stephen R. Bough
400 East Ninth Street, Room 7462
Kansas City, Missouri 64106

I further certify that the required four paper copies of this Response Brief with Appendix will be submitted to the Office of the Clerk, U. S. Court of Appeals for the Federal Circuit, 717 Madison Place, NW, Washington, D. C. 20439, via Federal Express delivery, in accordance with the Federal Circuit rules.

/s/ James J. Kernell
Counsel for Respondent